UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

ARTHUR SMITH, Individually and On Behalf of All Others Similarly Situated, Plaintiff, vs. KERYX BIOPHARMACEUTICALS, INC. and RON BENTSUR, Defendants.	Civil Action No: 1:13-cv-00755-TPG AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS **JURY TRIAL DEMANDED**

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The allegations in this Complaint are based upon Plaintiff's personal knowledge as to Plaintiff's own acts, and are based upon information and belief as to all other matters alleged herein. Plaintiff's information and belief is based upon the investigation by Plaintiff's counsel into the facts and circumstances alleged herein, including without limitation, (i) review and analysis of public filings Keryx Biopharmaceuticals, Inc. ("Keryx" or the "Company") made with the United States Securities and Exchange Commission ("SEC") and the U.S. Food and Drug Administration ("FDA"); (ii) review and analysis of press releases, analyst reports, public statements, news articles and other publications disseminated by or concerning Keryx and the other defendant named herein (together with Keryx, the "Defendants"); (iii) review and analysis of Company conference calls, press conferences, corporate website, and related statements and materials; and (iv) consultation with experts specializing in oncology, biostatistics and FDA clinical trials. Many additional facts supporting the allegations herein are known only to the Defendants and/or are within their exclusive custody or control. Plaintiff believes that additional evidentiary support for the allegations herein will emerge after a reasonable opportunity to conduct discovery.

I. NATURE OF THE ACTION

1. This is a federal class action on behalf of investors who purchased or otherwise acquired Keryx securities in the United States or on the NASDAQ Capital Market ("NASDAQ CM") between June 1, 2009 and April 1, 2012, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act"), and Rule 10b-5 promulgated thereunder.

2. Keryx is a biopharmaceutical company focused on the acquisition, development and commercialization of pharmaceutical products.

3. Throughout the Class Period, Defendants misled investors about the timing and success of Keryx's clinical trial that tested whether perifosine was effective in treating late stage colorectal cancer, and the likelihood that perifosine would be approved by the FDA. As a result, Keryx's stock traded at artificially inflated prices during the Class Period, reaching a high of $6.67 on May 4, 2010.

4. After the truth regarding perifosine's inability to treat colorectal cancer was disclosed to the public, unsuspecting investors watched the price of Keryx's common stock drop to $1.74 on April 2, 2012, a decline of approximately 74% from the Class Period high.

5. Through this action, Plaintiff seeks to recover for himself and absent Class members the devastating losses that were suffered as a result of the Company's and its officers' fraud.

II. JURISDICTION AND VENUE

6. This action arises under Sections 10(b) and 20(a) of the Exchange Act of 1934, as amended, 15 U.S.C. §§ 78j(b) and 78(t), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5, promulgated thereunder.

7. This Court has jurisdiction over the action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

8. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

9. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

III. THE PARTIES

A. Plaintiff

10. Plaintiff Arthur Smith, as set forth in his shareholder certification and incorporated by reference herein (ECF No. 1), purchased Keryx securities at artificially inflated prices during the Class Period and has been damaged thereby.

B. Keryx Biopharmaceuticals, Inc.

11. Defendant Keryx is headquartered in New York, New York. The Company is currently engaged in the acquisition, development and commercialization of pharmaceutical products. The Company has common stock listed on the NASDAQ CM, which trades under the ticker symbol "KERX."

C. Ron Bentsur

12. Defendant Ron Bentsur ("Bentsur") is and was, at all relevant times, the Company's Chief Executive Officer ("CEO") and Director.

D. Bentsur's Duties

13. Bentsur, because of his positions with the Company, had the authority to control, correct and/or update the contents of Keryx's public disclosures to the market. Bentsur had the duty to exercise due care and diligence and the duty of full and candid disclosure of all material facts relating to the Company's development of perifosine, the safety and efficacy of the drug, and Phase 2 and Phase 3 trial results. Bentsur further had the duty to correct and/or update any previously issued statements that became materially misleading or untrue, so that the market price of the Company's publicly traded securities linked thereto would be based upon truthful, complete and accurate information. To discharge his duties, Bentsur was required to exercise reasonable and prudent supervision over the dissemination of information concerning the

Company's development of perifosine. By virtue of such duties, Bentsur was required, *inter alia*, to:

a. conduct and supervise the business of Keryx in accordance with federal laws;

b. supervise the preparation of Keryx's SEC filings and approve any reports concerning Keryx's financial reporting and results; and

c. ensure that Keryx established and followed adequate internal controls.

14. As an officer and/or controlling person of a publicly-held company which is registered with the SEC under the federal securities laws and the securities of which are traded on the NASDAQ CM and governed by the provisions of the federal securities laws, Bentsur had a duty to: (i) promptly disseminate accurate and truthful information with respect to perifosine's clinical trials; (ii) correct any previously issued statements that were materially misleading or untrue so that the market could accurately price the Company's publicly traded securities based upon truthful, accurate and complete information; and (iii) update any previously issued statements that became materially misleading or untrue so that the market could accurately price the Company's publicly traded securities based upon truthful, accurate and complete information.

15. Bentsur is primarily liable for the misrepresentations and misleading statements alleged and is also liable as controlling person of Keryx. The scheme deceived the investing public regarding Keryx's financial and operational condition and the ability of perifosine to treat patients with colorectal cancer, and caused Plaintiff and other members of the Class to purchase or sell Keryx securities at artificially inflated prices during the Class Period and suffer damages as a result.

IV. CLASS ACTION ALLEGATIONS

16. Plaintiff brings this action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of himself and a class (the "Class") consisting of all persons who purchased or otherwise acquired Keryx securities in the United States or on the NASDAQ CM during the Class Period at artificially inflated prices, including but not limited to Keryx securities, during the Class Period, and who were damaged thereby. Excluded from the Class are the Defendants named herein, members of their immediate families, any firm, trust, partnership, corporation, officer, director or other individual or entity in which a Defendant has a controlling interest or which is related to or affiliated with any of the Defendants, and the legal representatives, heirs, successors-in-interest or assigns of such excluded persons.

17. Members of the Class are so numerous and geographically dispersed that joinder of all members is impracticable. While the exact number of Class members remains unknown at this time, Plaintiff believes that there are hundreds, if not thousands, of members of the Class. Record owners and Class members can be identified from records maintained by Keryx, or its transfer agent, and can be notified of the pendency of this action by mail and publication, using forms of notice similar to those customarily used in securities class actions.

18. Plaintiff's claims are typical of the other members of the Class because Plaintiff and all members of the Class sustained damages that arose out of the Defendants' unlawful conduct complained of herein.

19. Plaintiff will fairly and adequately protect the interests of the members of the Class, and Plaintiff has no interests that are contrary to, or in conflict with, the interests of the Class members that he seeks to represent. Plaintiff has retained competent counsel experienced in class action litigation under the federal securities laws to ensure such protection and intends to prosecute this action vigorously.

20. A class action is superior to other methods for the fair and efficient adjudication of this controversy since joinder of all members of the Class is impracticable. Furthermore, as the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually seek redress for wrongs done to them. There will be no difficulty in the management of this action as a class action.

21. The prosecution of separate actions by individual Class members would create a risk of inconsistent and varying adjudications, which could establish incompatible standards of conduct for Defendants. Questions of law and fact common to members of the Class predominate over any questions that may affect only individual members, in that Defendants have acted on grounds generally applicable to the entire Class. The questions of law and fact common to the Class include, but are not limited to, the following:

a. whether Defendants' acts violated the federal securities laws as alleged herein;

b. whether Defendants' publicly disseminated statements during the Class Period omitted and/or misrepresented material facts;

c. whether Defendants acted with scienter in omitting and/or misrepresenting material facts;

d. whether the price of Keryx securities was artificially inflated during the Class Period as a result of the material misrepresentations and omissions complained of herein;

e. whether Bentsur was a controlling persons as alleged herein; and

f. whether members of the Class have sustained damages and, if so, the proper measure of such damages.

V. BACKGROUND

A. Company Background

22. Paramount Pharmaceuticals, Inc. was incorporated as a Delaware Corporation in October 1998 and subsequently changed its name to Lakaro Biopharmaceuticals, Inc. ("Lakaro") in November 1999. In 2000, Lakaro changed its name to Keryx Biopharmaceuticals Inc. and conducted an Initial Public Offering.

23. On April 4, 2008, Keryx announced that it was implementing a "strategic restructuring plan to reduce its cash burn rate and re-focus its development efforts" (the "2008 Restructuring") following the failure of its Phase 3 clinical trial for Sulonex™, a drug used to treat diabetic neuropathy. As part of this restructuring, Keryx planned to cut its workforce in half; terminate 12 of 20 early-stage clinical studies of KRX-0401 (perifosine); eliminate the position of President of the Company altogether; and close two offices and one manufacturing suite. Through this restructuring plan, Keryx strove to reduce its cash burn rate to approximately $10-$15 million for the remainder of 2008.

24. On April 25, 2008, Keryx announced that it received notice, three days earlier, that it faced delisting from the NASDAQ Global Market ("NASDAQ GM") pursuant to Marketplace Rule 4450(a)(5) ("the minimum bid price rule") for falling below the $1.00 minimum bid price for 30 consecutive business days. NASDAQ informed Keryx that it would have 180 calendar days to regain compliance. In response, Keryx planned to apply to transfer to the NASDAQ CM so that it would no longer be subject to the NASDAQ GM's requirements. On October 23, 2008, Keryx announced that NASDAQ extended the minimum bid price compliance period giving the Company until January 23, 2009 to regain compliance.

25. On November 21, 2008, Keryx announced that it received notice that the Company faced delisting from the NASDAQ CM pursuant to Marketplace Rule 4310(c)(3) ("the

minimum market value rule") as it had less than $2.5 million in stockholders' equity, $35 million market value of listed securities or $500,000 of net income from continuing operations for the most recently completed fiscal year or two of the three most recently completed fiscal years.

26. On March 5, 2009, Keryx announced that the Company's common stock was scheduled to be delisted from the NASDAQ CM on March 12, 2009 due to its noncompliance with the minimum market value rule, which Keryx appealed. On June 9, 2009, NASDAQ CM granted the Company yet another extension, this time through August 31, 2009, to regain compliance.

27. On March 12, 2009, Keryx announced that as of December 31, 2008, it had cash, cash equivalents, short-term investment securities and interest receivable of $15.5 million (in addition to $7.2 million of auction rate securities), as compared to $62.4 million on December 31, 2007.

28. On April 3, 2009, the Audit Committee of the Board of Directors of Keryx approved the dismissal of KPMG LLP as the Company's independent registered public accounting firm. On April 9, 2009, Keryx filed an 8-K which stated, in relevant part:

> The audit reports of KPMG LLP on the consolidated financial statements of Keryx Biopharmaceuticals, Inc. and subsidiaries as of and for the years ended December 31, 2008 and 2007, did not contain any adverse opinion or disclaimer of opinion, nor were they qualified or modified as to uncertainty, audit scope, or accounting principles, except that KPMG's report on the consolidated financial statements of Keryx Biopharmaceuticals, Inc. and subsidiaries as of and for the year ended December 31, 2008 contained separate paragraphs stating:
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> "The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. ***As discussed in Note 1 to the consolidated financial statements, the Company has incurred substantial recurring losses from operations, a deficiency in equity, limited cash, cash equivalents, and short-term investment securities, and illiquid investments in auction rate securities that raise substantial doubt about its ability to continue as a going concern.*** Management's plans in regard to these matters are also described in Note 1. The consolidated financial

statements do not include any adjustments that might result from the outcome of this uncertainty."

29. On April 23, 2009, the Board of Directors of Keryx voted to terminate the employment of its then current Chairman and CEO, Michael S. Weiss. On May 20, 2009, Keryx appointed Defendant Bentsur as the Company's CEO.

30. In sum, in 2009, just before Keryx began praising the positive data from its Phase 2 clinical trial of perifosine with respect to colorectal cancer, Keryx had limited assets and faced substantial losses, the lingering burden of adapting to the 2008 Restructuring, the failure of Sulonex™—one of its primary drug candidates in Phase 3 testing—and a stock price that was languishing to the point that the Company was facing de-listing of its stock by the NASDAQ CM. Defendants' solution to Keryx's precarious situation was its purportedly "novel anticancer agent" perifosine, which had languished in clinical trials for over 10 years, with at best mixed results.

B. Nature and History of Perifosine

31. Perifosine is a derivative of miltefosine, a topical treatment for cancer developed in the 1980's, and is a phospholipid derivative of alkylphosphocholine. Perifosine's potential value as a cancer treatment stems from its toxicity to cell membranes. This membrane toxicity leads to a whole host of cellular insults, including effects on Akt,[1] MAPK and KNL signaling cascades. This targeting of the cellular membrane which results in disruption of multiple signaling cascades is a very non-specific approach to cancer treatment which was developed without any understanding of Akt, leading some to refer to such a drug as a "dirty" drug.

[1] Akt, also known as protein Kinase B, is a serine/threonine–specific protein Kinase that plays a key role in multiple cellular processes such as glucose metabolism, apoptosis, cell proliferation, transcription and cell migration.

32. Various clinical trials of perifosine were conducted beginning no later than 1998, including Phase 2 studies of perifosine as both a single agent and in combination with several forms of anti-cancer treatments for a broad spectrum of malignancies. These trials, which were very limited in scope and size, showed mixed results, with some claiming "encouraging" results, while others have been called at best "sobering."

C. Keryx's License Agreement with Æterna Zentaris

33. Perifosine was developed by Asta Medica, the predecessor to biopharmaceutical company Zentaris AG ("Zentaris"), in the 1990's under the direction of Juergen Engel, former CEO of Zentaris. On May 26, 2004, Æterna Laboratories, Inc. acquired Zentaris and renamed itself Æterna Zentaris Inc. ("Æterna"). At this time, Zentaris had already entered into a License and Cooperation Agreement for Perifosine ("License Agreement") with Keryx's wholly owned subsidiary, AOI Pharma, Inc. Under the License Agreement, as amended by an Addendum dated December 5, 2003, Keryx and Zentaris (and subsequently Æterna) agreed to be jointly responsible for the pharmaceutical development of perifosine and jointly liable for the costs of development. In exchange for Keryx's development efforts, Keryx received a license for the sale of perifosine in North America. Under the License Agreement, Keryx was responsible for conducting and testing perifosine in North America, and all development of the drug was controlled by a coordination committee (the "Coordination Committee") consisting of two members from Keryx and Æterna.

D. Statistical Measures and Multiplicity Issues in Drug Trials

34. Evidence-based medicine depends on the systematic accumulation of information about how different treatments affect patients. Ideally, a cause-effect relationship can be established between treatments and outcomes in patients with specific diseases. The scientific method is the system underlying evidence-based medicine.

35. Specifically, the scientific method involves the formulation and testing of hypotheses that are capable of being proven false using a test of observed data. In evaluating new drugs, for example, modern statistical methods are used to test hypotheses. In hypothesis-testing, the so-called "null hypothesis" corresponds to a general or default position, which is typically a statement that no difference exists between the experimental and the control patient populations (*i.e.*, that a treatment has no effect).

36. Statisticians have developed a common vocabulary for the statistical measures they use to test their hypotheses. For example, a "p-value" is the statistical probability of the occurrence of a given finding by chance alone in comparison with the known distribution of possible findings, considering the kinds of data, the technique of analysis and the number of observations. P-values may be noted as a decimal: $p < .01$ means that the likelihood that the phenomena tested occurred by chance alone is less than 1%. Thus, the lower the p-value, the less likely that the finding would occur by chance alone. The null hypothesis (*i.e.*, that a treatment has no effect) is rejected when the p-value is less than a pre-determined significance level, which is represented by the symbol α and is ordinarily between 0.05 or 0.01 (5% or 1%). When the null hypothesis is rejected because the p-value is below the significance level α, in which case the treatment may be effective, the result is said to be "statistically significant."

37. In statistics, a Type I error is the rejection of a potentially true null hypothesis, or in other words a false positive result. The incidence of false positives is proportional to the number of tests performed and the critical significance level α (*i.e.*, the p-value cutoff).

38. Set forth below is a table illustrating the probability of one or more false positives (using an α of 0.05) based on the number of tests conducted:

Number of Tests Conducted (N)	Probability of At Least 1 False Positive by Chance ($100 * (1-0.95^N)$)
1	5%
2	9.75%
5	22.62%
10	40.13%
20	64.15%
100	99.41%

39. Consequently, the more hypotheses one tests, the more likely a false positive occurs. A clinical trial that fails to account for multiple hypothesis tests being performed (hereafter "multiplicity") underrepresents the likelihood that a false positive occurred.

40. Multiplicity in clinical trials appears under several different guises: multiple tests; multiple arms; multiple doses vs. the placebo; subgroup analysis; multiple endpoints; composite endpoints; multiple statistical approaches for the same endpoint; interim analysis; multiple looks at the data during interim analysis; meta analysis; and multiple trials.

41. It is well recognized by statisticians and nonstatisticians alike that multiplicity inflates the Type I error rate of the experiment, and this has prompted the development of multiple comparison adjustment procedures to properly account for the likelihood of false positives.

42. In fact, statisticians have developed several multiple testing corrections to limit false positives. For instance, the Bonferroni approach is a simple and effective method for ensuring that the overall Type I error rate of α is maintained when performing N hypothesis tests. The p-value for each test is simply multiplied by the number of tests performed. If the corrected p-value is still below the significance level α, the test is then considered statistically significant.

43. In fact, the FDA issued "Guidance for Industry: E9 Statistical Principles for Clinical Trials" ("FDA 1998 Guidance") in September 1998, which contains "statistical

principles" which expressly "should be applied as far as possible to all phases of clinical development," notes the following:

> When multiplicity is present, the usual frequentist approach to the analysis of clinical trial data may necessitate an adjustment to the Type I error [*i.e.*, the rejection of a potentially true null hypothesis]. Multiplicity may arise, for example, from multiple primary variables . . . , multiple comparisons of treatments, repeated evaluation over time, and/or interim analyses. . . . Methods to avoid or reduce multiplicity are sometimes preferable when available, such as the identification of the key primary variable (multiple variables), the choice of a critical treatment contrast (multiple comparisons), and the use of a summary measure such as *area under the curve* (repeated measures).
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> . . . .
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> If hypothesis tests are used, statistical adjustments for multiplicity to quantify the Type I error are appropriate, but the Type II error is usually of more concern. ***Care should be taken when interpreting putative statistically significant findings when there is no multiplicity adjustment.***

FDA 1998 Guidance, at 33, 36.[2]

44. With respect to subgroup analysis, the FDA 1998 Guidance further provides:

> In most cases, however, ***subgroup or interaction analyses are exploratory and should be clearly identified as such; they should explore the uniformity of any treatment effects found overall.*** In general, such analyses should proceed first through the addition of interaction terms to the statistical model in question, complemented by additional exploratory analysis within relevant subgroups of subjects, or within strata defined by the covariates. When exploratory, these analyses should be interpreted cautiously. Any conclusion of treatment efficacy (or lack thereof) or safety based solely on exploratory subgroup analyses is unlikely to be accepted.

Id. at 34.

45. The European Agency for the Evaluation of Medicinal Products ("EMEA") similarly notes in its "Points to Consider on Multiplicity Issues in Clinical Trials" ("EMEA Multiplicity Guidance") issued on September 19, 2002:

> In clinical studies it is often necessary to answer more than one question about the efficacy (or safety) of one or more treatments in a specific disease, because the success of a drug development program may depend on a positive answer to more than a single

[2] All emphasis is added unless otherwise noted.

> question. ***It is well known that the chance of spurious positive chance finding increases with the number of questions posed, if no actions are taken to protect against the inflation of false positive findings from multiple statistical tests. In this context, concern is focused on the opportunity to choose favourable results from multiple analyses. It is therefore necessary that the statistical procedures planned to deal with, or to avoid, multiplicity are fully detailed in the study protocol or in the statistical analysis plan to allow an assessment of their suitability and appropriateness***.

EMEA Multiplicity Guidance, at 10.

46. Because of the multiplicity concerns inherent in multiple testing and subgroups:

> ***A specific claim of a beneficial effect in a particular subgroup requires pre-specification of the corresponding null hypothesis and an appropriate confirmatory analysis strategy. It is highly unlikely that claims based on subgroup analysis would be accepted in the absence of a significant effect for the overall study population.***

Id. at 7.

E. The Phase 2 Testing of Perifosine Was Manipulated

47. In 2007, Keryx and Æterna, its development partner for perifosine, began recruiting for an "exploratory" Phase 2 placebo-controlled study of perifosine in combination with other single agent chemotherapies for metastatic cancer patients. Given the fact that it was still uncertain which types of tumors perifosine might effectively treat, this exploratory Phase 2 study included patients with ***at least*** seven different types of metastatic cancer (breast, non-small cell lung, colorectal, prostate, ovarian, head and neck, and soft tissue sarcoma), which were treated in combination with (i) either perifosine or a placebo and (ii) one of eight other chemotherapy regimens (paclitaxel (at 2 different doses), docetaxel (at 2 different doses), gemcitabine, doxorubicin, pegylated liposomal doxorubicin, capecitabine, pemetrexed and irinotecan), all divided into different "arms" of the study. Moreover, several of the chemotherapy regimens were approved for treatment in multiple forms of metastatic cancer. For example, capecitabine was approved for treatment in metastatic breast cancer as well as metastatic colon cancer. The multiple arms of the study inherently increased the chances for a

false positive conclusion, *i.e.*, a spurious finding that perifosine provided a statistically significant benefit to colorectal cancer patients. The protocol for this Phase 2 study was divided into two stages. The protocol called for the enrollment of approximately 50 patients across the U.S. in each arm of the study for Stage 1, the hypothesis generating stage of the study. Keryx never disclosed the number of different arms of this study, but given a minimum of seven types of cancer combined with eight different drugs which could be used for treatment of various types of cancer and the varying dosages, there were a minimum of ten arms and possibly dozens more.

48. The "Primary Study Objective[]" of the trial was "[t]o determine the proportion of patients progression free at 6 months when receiving single agent chemotherapy in combination with perifosine in comparison to patients receiving single agent chemotherapy alone (i.e., with placebo)." The original "Secondary Study Objectives" of the study were "[t]o determine the toxicity of single agent chemotherapy in combination with perifosine" and "[t]o compare the time to progression of chemotherapy in combination with placebo to historical experience."

49. According to the protocol, if after the completion of Stage 1, more than 30% of perifosine treated patients were progression-free, the study would be expanded into Stage 2, the hypothesis confirming stage of the study. Stage 1, however, was unexpectedly stopped early, all patients were unblinded and an unplanned interim analysis of the safety and efficacy between the perifosine treatment group and the placebo treatment group was performed prematurely. In fact, enrollment had not been completed and the treatment protocols for the enrollees had not been completed. Indeed, with respect to the capecitabine/colorectal arm of the study, only 25 of the planned 50 patients had been enrolled. Keryx never disclosed either the number of arms or the number of patients enrolled in each of the other arms, but, in total, the enrollment reached 381 patients for all arms of the study. Again, however, it is unknown how many of these 381

enrollees completed the course of treatment called for under the protocol. Moreover, Keryx never disclosed the results from Stage 1 overall or for any of the treatment arms other than the capecitabine arm or subgroup for patients with metastatic colorectal cancer.

50. This premature termination of Stage 1 amounted to little more than a data mining expedition to identify any arm or subgroup thereof that offered any glimmer of hope for treating some type of cancer. By slicing and dicing the data every way possible, the Company cherry-picked 25 out of 381 patients in the protocol who had been treated previously with two (no more or less) prior treatment regimens and who had completed the treatment to progression in the hopes of supporting a hypothesis that perifosine provided a clinical benefit for the treatment of some kind of cancer. Based upon this preliminary data dredging, all investigators in the trial were sent a Hold On Enrollment immediately terminating all treatments under the protocol for every other combination of cancer and chemotherapy treatments other than the capecitabine arm and the docetaxel arm.

51. For Stage 2 of this Phase 2 trial, enrollment and treatment were continued only in the capecitabine arm or subgroup for patients with metastatic colorectal cancer, which at that point had only enrolled 25 of the 50 patients called for under the protocol.[3] Keryx never disclosed whether the capecitabine arm or subgroup for patients with metastatic colorectal cancer reached the Primary Study Objective, *i.e.*, 30% of the enrollees progression free at 6 months prior to the unblinding of the data and patients. Likewise, Keryx never disclosed any results for the capecitabine arm or subgroup for patients with metastatic breast cancer. Ultimately, only an additional 13 patients with metastatic colorectal cancer were enrolled in Stage 2 of the trial. In contravention of accepted testing procedures, and undisclosed to investors, the 25 already

[3] Enrollment for the docetaxel arm was closed, but investigators were permitted to complete the treatment until progression under the protocol.

unblinded patients from the Stage 1 testing were included in the Stage 2 testing of the capecitabine arm for patients with metastatic colorectal cancer. In effect, 25 Stage 1 enrollees were cherry-picked out of a total test population of 381 not only to generate the hypothesis, but also to confirm that same hypothesis in Stage 2. The inclusion of the 25 unblinded enrollees in the confirmatory stage of the Phase 2 trial introduced the very bias that a true double blind study is designed to eliminate. Nevertheless, Defendants continued to represent to investors throughout the Class Period that the Phase II trial was a double blind study, even though they knew the results for 25 out of the 38 – ***or 66% of the enrollees*** – before Primary and Secondary Study Objectives for the confirmatory stage of the Phase II trial were established. Not surprisingly, the results from the 25 already unblinded patients showed a statistically significant benefit from the perifosine/capecitabine ("P-CAP") treatment, even when the results from the 13 additional enrollees showed no such benefit. For example, the 25 unblinded patients showed a statistically significant 71% improvement in overall survival ("OS") in the P-CAP arm versus the placebo arm, while the 13 patients randomly assigned after the unblinding and the interim analysis, showed no statistically significant benefit from the P-CAP treatment as compared to the placebo arm.[4] Nevertheless, as detailed below, throughout the Class Period, Defendants repeatedly represented that the Phase II trial showed a statistically significant improvement in overall survival, without disclosing that no such benefit appeared in the Stage 2 enrollees. Moreover, after the results for Phase 2 were unblinded, an unknown number of sub-group statistical analyses were performed to find other indications of clinical benefit from the treatment with perifosine and capecitabine.

[4] Keryx has never revealed whether other statistical differences existed between the results from the 25 unblinded patients and the 13 subsequent enrollees.

52. On May 9, 2011, ***after the data from Phase 2 was unblinded and this unknown number of statistical analyses were performed***, Defendants changed both the Primary Study Objective and the Secondary Study Objectives of the study to fit the results. Without disclosing whether the capecitabine arm for patients with metastatic colorectal cancer ever reached the original Primary Study Objective, i.e., 30% progression free at 6 months, the Primary Study Objective was changed as follows: "To determine the time to tumor progression when receiving single agent chemotherapy (capecitabine) in combination with perifosine in comparison to patients receiving single agent chemotherapy (capecitabine) alone (i.e., with placebo)." Also, another Secondary Study Objective was added: "Overall survival will also be evaluated."

53. Additionally, despite the multiple arms of the study and the multiple subgroup analyses, all hypotheses tested were analyzed at a 0.05 significance level and the p-values were not adjusted for the unplanned interim analyses, the multiplicity issues present in the trial or the multiple analyses performed on the data after it had been unblinded.

54. In short, with the unanimous consent of the Keryx representatives on the Coordinating Committee responsible for developing perifosine, the Phase 2 study was manipulated in complete contravention of the protocol to find some form of cancer for which perifosine would purportedly provide a statistically significant clinical benefit. First, Stage 1 of the study contained an undisclosed number of treatment arms and the results for all treatment arms other than the capecitabine arm or subgroup for patients with metastatic colorectal cancer were neither disclosed nor factored into or adjusted for in the statistical analysis. Second, Stage 1 was terminated prematurely and the data was dredged to find 25[5] out of 381 enrollees – ***just 6.6%*** – of the total enrollees who had completed the treatment to progression that would

[5] Presumably, roughly half of these 25 patients were given the placebo.

purportedly support a theory that perifosine provided a clinical benefit to some subset of cancer patients. Third, the majority of the enrollees in the Stage 2 hypothesis confirming stage of the study were the Stage 1 enrollees used to generate the hypothesis, effectively preordaining the desired result, necessarily introducing bias into the study. Fourth, after all of the patients were unblinded and more than 16 months after the results had been announced to investors, Defendants changed both the Primary Study Objective and the Secondary Study Objectives to fit the known results. Finally, in the statistical analysis of the data, the number of testing arms and the results from all arms other than the capecitabine arm or subgroup for patients with metastatic colorectal cancer were not disclosed and no statistical adjustments were performed to correct for the host of multiplicity issues present and the multiple ad hoc analyses performed.

VI. SUBSTANTIVE ALLEGATIONS

55. The Class Period begins on June 1, 2009, when Keryx issued a press release announcing positive FDA Phase 2 trial data on the clinical activity of perifosine as a treatment for advanced metastatic colon cancer. The press release stated, in relevant part, the following:

> ***Keryx Biopharmaceuticals Announces Positive Data from a Randomized, Multi-Center, Placebo-Controlled, Phase 2 Combination Study of KRX-0401 (Perifosine) in the Treatment of Advanced Metastatic Colon Cancer***
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> KRX-0401 + Capecitabine More Than Doubles Time to Progression and Overall Response Rate as well as Extends Overall Survival vs. Capecitabine + Placebo in Patients with 2nd or 3rd Line Metastatic Colon Cancer
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> NEW YORK, June 1 /PRNewswire-FirstCall/ -- Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX) yesterday announced data on the clinical activity of KRX-0401 (perifosine), the Company's Akt-inhibitor for cancer, in combination with capecitabine as a treatment for advanced colon cancer. Abstract #4081, entitled, "Randomized phase II study of perifosine in combination with capecitabine versus capecitabine alone in patients with second- or third-line metastatic colon cancer," was presented yesterday in a poster during the Gastrointestinal Cancer -- Colorectal session at the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO), taking place in Orlando, Florida.
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> ***In this randomized, double-blind, placebo-controlled study conducted at 11 centers across the United States, patients with 2nd or 3rd line metastatic colon cancer were***

randomized to receive capecitabine (Xeloda®), an approved drug for metastatic colon cancer, at a dose of 825 mg/m2 BID (total daily dose of 1650 mg/m2) on days 1-14 every 21 days, plus either perifosine or placebo at 50 mg daily. Treatment was continued until progression. ***The study enrolled a total of 38 patients, of which 35 patients were evaluable for response (20 patients on the capecitabine + perifosine arm and 15 patients on the capecitabine + placebo arm).*** The three patients not evaluable for response were all in the capecitabine + placebo arm; 2 patients were inevaluable due to toxicity (days 14, 46) and 1 patient was inevaluable due to a new malignancy on day 6.

The median prior treatment regimens was two, with prior treatment regimens as follows: 91% of the patients received prior FOLFIRI (Irinotecan + 5FU + Leucovorin); 74% prior FOLFOX (Oxaliplatin + 5FU + Leucovorin); 63% were previously treated with both FOLFIRI and FOLFOX; 77% received prior Avastin®; and 43% prior Erbitux®. Prior treatment with single agent capecitabine was excluded.

The primary endpoints of this study were to measure 1) Time to Progression (TTP); 2) Overall Response Rate (ORR), defined as the percentage of patients achieving a Complete Response (CR) or Partial Response (PR) by RECIST, and 3) Clinical Benefit Rate (CBR) defined as the percentage of patients on treatment for greater than three months with at least stable disease. Safety of perifosine + capecitabine vs. capecitabine + placebo in this patient population was evaluated as a secondary endpoint. Perifosine in combination with capecitabine was well tolerated with hand/foot syndrome (14%) and anemia (11%) as the highest reported grade 3/4 adverse events.

Best response and median time to progression of capecitabine + perifosine vs. capecitabine + placebo were as follows:

Group	N	CR N(%)	PR N(%)	ORR N(%)	SD>12 wks N(%)	CBR N(%)	Median TTP (wks)
Capecitabine + Perifosine	20	1 (5%)	3 (15%)	4 (20%)	11 (55%)	15 (75%)	28.9 weeks {95% CI (13, 48.1)}
Capecitabine + Placebo	15	0	1 (7%)	1 (7%)	5 (33%)	6 (40%)	11 weeks {95% CI (9, 15.9)}

Perifosine + capecitabine more than doubled time to progression vs. capecitabine + placebo with a statistically significant p-value = 0.0006. In addition, perifosine + capecitabine more than doubled the ORR and almost doubled the Clinical Benefit Rate vs. capecitabine + placebo.

Although not a primary endpoint in the study, overall survival was analyzed with results as follows:

Group	Median Overall Survival* (months)	% change
Capecitabine + Perifosine	22 {95% CI (12.1, NR)}	26% Increase**
Capecitabine + Placebo	16.3 {95% CI (5.3, 17.1)}	

*Survival calculated from date of randomization until date of death from any cause, whether or not additional therapies were received after removal from treatment.
**As of May 2009, median overall survival in the perifosine + capecitabine patient group is ongoing with 10 of the 20 patients in this arm still alive.

Dr. Howard Burris, Chief Medical Officer and Director of Drug Development for the Sarah Cannon Research Institute, Nashville TN, an investigator involved in the Keryx-sponsored perifosine clinical program since 2004, remarked, "***The results demonstrate that the addition of perifosine to capecitabine more than doubled time to progression and response rates, along with extending survival vs. capecitabine alone***. ***Although not a large sample size, the data here is very interesting and next steps should be considered***."

Ron Bentsur, Chief Executive Officer of Keryx, commented, "Patients with advanced metastatic colon cancer, who fail standard first and second line treatment, are truly in need of additional therapies. ***We are excited about the data as the combination of perifosine and capecitabine, two oral agents, appears to demonstrate superior clinical benefit over capecitabine alone in this advanced patient population***. We will now explore plans to move this program forward in patients with advanced colorectal cancer." Mr. Bentsur added, "We wish to thank all the study investigators for their dedication to this clinical trial."

56. The aforementioned statements in ¶ 55 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

c. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

57. On August 12, 2009, Keryx filed Form 10-Q ("August 2009 10-Q") with the SEC announcing its financial results for the fiscal quarter ending June 30, 2009. It stated, in relevant part, the following:

> In June 2009, we announced ***positive data*** from a randomized, multi-center, placebo-controlled, Phase 2 study of KRX-0401 (perifosine) in combination with capecitabine (Xeloda®) versus capecitabine plus placebo in patients with second- or third-line metastatic colon cancer. The data was presented in a poster during the Gastrointestinal Cancer — Colorectal session at the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO), held in Orlando, Florida. ***In this randomized, double-blind, placebo-controlled study conducted at 11 centers across the United States, patients with 2nd or 3rd line metastatic colon cancer were randomized to receive capecitabine (Xeloda®), an approved drug for metastatic colon cancer, at a dose of 825 mg/m^2 BID (total daily dose of 1650 mg/m^2) on days 1 to 14 every 21 days, plus either KRX-0401 (perifosine) or placebo at 50 mg daily***. Treatment was continued until progression. ***The study enrolled a total of 38 patients, of which 35 patients were evaluable for response (20 patients on the capecitabine plus perifosine arm and 15 patients on the capecitabine plus placebo arm)***. The three patients not evaluable for response were all in

the capecitabine plus placebo arm; 2 patients were inevaluable due to toxicity (days 14, 46) and 1 patient was inevaluable due to a new malignancy on day 6.

The median prior treatment regimens was two, with prior treatment regimens as follows: 91% of the patients received prior FOLFIRI (Irinotecan + 5FU + Leucovorin); 74% prior FOLFOX (Oxaliplatin + 5FU + Leucovorin); 63% were previously treated with both FOLFIRI and FOLFOX; 77% received prior Avastin®; and 43% prior Erbitux®. Prior treatment with single agent capecitabine was excluded.

The primary endpoints of this study were to measure 1) Time to Progression (TTP); 2) Overall Response Rate (ORR), defined as the percentage of patients achieving a Complete Response (CR) or Partial Response (PR) by RECIST, and 3) Clinical Benefit Rate (CBR) defined as the percentage of patients on treatment for greater than three months with at least Stable Disease. Safety of perifosine plus capecitabine vs. capecitabine + placebo in this patient population was evaluated as a secondary endpoint. Perifosine in combination with capecitabine was well tolerated with hand/foot syndrome (14%) and anemia (11%) as the highest reported grade 3/4 adverse events.

Perifosine plus capecitabine more than doubled time to progression vs. capecitabine + placebo with a statistically significant p-value = 0.0006. In addition, perifosine plus capecitabine more than doubled the ORR and almost doubled the Clinical Benefit Rate vs. capecitabine plus placebo.

Best response and median time to progression of capecitabine plus perifosine vs. capecitabine plus placebo were as follows:

Group	n	CR n(%)	PR n(%)	ORR n(%)	Stable Disease> 12 wks n(%)	CBR* n(%)	Median TTP (wks)
Xeloda + Perifosine	20	1 (5%)	3 (15%)	4 (20%)	11 (55%)	15 (75%)	28.9 weeks {95% CI (13, 48.1)}
Xeloda + Placebo	15	0	1 (7%)	1 (7%)	5 (33%)	6 (40%)	11 weeks {95% CI (9, 15.9)}

*CBR: Clinical Benefit Rate as defined by ORR + Stable Disease

Perifosine plus capecitabine more than doubled time to progression vs. capecitabine + placebo with a statistically significant p-value = 0.0006. In addition, perifosine plus capecitabine more than doubled the ORR and almost doubled the Clinical Benefit Rate vs. capecitabine plus placebo.

Although not a primary endpoint in the study, overall survival was analyzed with results as follows:

Group	Median (months) Overall Survival*	% change
Xeloda + Perifosine	22 [95% CI (12.1, NR)]	35% Increase**
Xeloda + Placebo	16.3 [95% CI (5.3, 17.1)]	

* Survival calculated from date of randomization until date of death from any cause, whether or not additional therapies were received after removal from treatment.
**As of May 2009, median overall survival in the perifosine plus capecitabine patient group is ongoing with 10 of the 20 patients in this arm still alive.

58. The aforementioned statements in ¶ 57 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

c. Defendants knew or recklessly disregarded the fact that the 13 patients

enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

59. The August 2009 10-Q was certified by Defendant Bentsur, who respectively attested to the following:

> 1. I have reviewed this quarterly report on Form 10-Q of Keryx Biopharmaceuticals, Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
>
> 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
>
> 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
>
> > a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
> >
> > b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
> >
> > c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

> d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
>
> 5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
>
> a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
>
> b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

60. Additionally, Defendant Bentsur certified under Section 906 of the Sarbanes-Oxley Act of 2002 that the "information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

61. On August 28, 2009, Keryx filed with the SEC a registration statement on Form S-3 in order to issue up to $40 million of the Company's common shares and/or warrants. On September 23, 2009, Keryx filed a prospectus ("September 2009 Prospectus") with the SEC in order to issue up to $40 million of the Company's common shares and/or warrants. The September 2009 Prospectus incorporated by reference the August 2009 10-Q referenced in ¶¶ 57-59. Then on September 30, 2009, Keryx filed with the SEC a Prospectus Supplement ("September 2009 Prospectus Supplement"), which incorporated by reference the September 2009 Prospectus, and announced the direct offering of 8 million units to institutional investors. One unit was comprised of one share of common stock and one warrant to purchase 0.35 of a share of common stock. Each unit was priced at $2.50 and the warrants had an exercise price of

$2.65. On November 9, 2009, Keryx announced that, pursuant to the September 2009 Prospectus Supplement, it raised $18.4 million in net proceeds ($20 million in gross proceeds).

62. On November 10, 2009, the Company filed Form 10-Q ("November 2009 10-Q") with the SEC announcing its financial results for the fiscal quarter ending September 30, 2009. The November 2009 10-Q stated, in relevant part, the following:

> In June 2009, we announced ***positive data*** from a randomized, multi-center, placebo-controlled, Phase 2 study of KRX-0401 (perifosine) in combination with capecitabine (Xeloda®) versus capecitabine plus placebo in patients with second- or third-line metastatic colon cancer.
>
> The data was presented in a poster during the Gastrointestinal Cancer — Colorectal session at the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO), held in Orlando, Florida. ***In this randomized, double-blind, placebo-controlled study conducted at 11 centers across the United States, patients with 2nd or 3rd line metastatic colon cancer were randomized to receive capecitabine (Xeloda®), an approved drug for metastatic colon cancer, at a dose of 825 mg/m^2 BID (total daily dose of 1650 mg/m^2) on days 1 to 14 every 21 days, plus either KRX-0401 (perifosine) or placebo at 50 mg daily***. Treatment was continued until progression. ***The study enrolled a total of 38 patients, of which 35 patients were evaluable for response (20 patients on the capecitabine plus perifosine arm and 15 patients on the capecitabine plus placebo arm)***. The three patients not evaluable for response were all in the capecitabine plus placebo arm; 2 patients were inevaluable due to toxicity (days 14, 46) and 1 patient was inevaluable due to a new malignancy on day 6.
>
> The median prior treatment regimens was two, with prior treatment regimens as follows: 91% of the patients received prior FOLFIRI (Irinotecan + 5FU + Leucovorin); 74% prior FOLFOX (Oxaliplatin + 5FU + Leucovorin); 63% were previously treated with both FOLFIRI and FOLFOX; 77% received prior Avastin®; and 43% prior Erbitux®. Prior treatment with single agent capecitabine was excluded.
>
> The primary endpoints of this study were to measure 1) Time to Progression (TTP); 2) Overall Response Rate (ORR), defined as the percentage of patients achieving a Complete Response (CR) or Partial Response (PR) by RECIST, and 3) Clinical Benefit Rate (CBR) defined as the percentage of patients on treatment for greater than three months with at least Stable Disease. Safety of perifosine plus capecitabine vs. capecitabine + placebo in this patient population was evaluated as a secondary endpoint. Perifosine in combination with capecitabine was well tolerated with hand/foot syndrome (14%) and anemia (11%) as the highest reported grade 3/4 adverse events.
>
> Best response and median time to progression of capecitabine plus perifosine vs. capecitabine plus placebo were as follows:

Group	n	CR n (%)	PR n (%)	ORR n (%)	Stable Disease> 12wks n (%)	CBR* n (%)	Median TTP (wks)
Xeloda + Perifosine	20	1 (5%)	3 (15%)	4 (20%)	11 (55%)	15 (75%)	28.9 weeks {95% CI (13, 48.1)}
Xeloda + Placebo	15	0	1 (7%)	1 (7%)	5 (33%)	6 (40%)	11 weeks {95% CI (9, 15.9)}

*CBR: Clinical Benefit Rate as defined by ORR + Stable Disease

Perifosine plus capecitabine more than doubled time to progression vs. capecitabine + placebo with a statistically significant p-value = 0.0006. In addition, perifosine plus capecitabine more than doubled the ORR and almost doubled the Clinical Benefit Rate vs. capecitabine plus placebo.

Although not a primary endpoint in the study, overall survival was analyzed with results as follows:

Group	Median Overall Survival*	% change
Xeloda + Perifosine	22 months [95% CI (12.1, NR)]	35% increase**
Xeloda + Placebo	16.3 months [95% CI (5.3, 17.1)]	

* Survival calculated from date of randomization until date of death from any cause, whether or not additional therapies were received after removal from treatment.
** As of September 2009, median overall survival in the perifosine plus capecitabine patient group is ongoing with 9 of the 20 patients in this arm still alive.

63. The aforementioned statements in ¶ 62 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine

would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

c. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

64. The November 2009 10-Q was also certified by Defendant Bentsur, who respectively attested to the accuracy thereof in the same form and content, except for the date of the report, set forth in ¶ 59 preceding with respect to the August 2009 10-Q.

65. On January 25, 2010, the Company issued a press release reporting the updated results of the Phase 2 study. The press release stated, in relevant part, the following:

> ***Keryx Reports Statistically Significant Benefit in Survival from Updated Results of a Randomized, Double-Blind, Placebo-Controlled Phase 2 Study of KRX-0401 (Perifosine) in the Treatment of Advanced Metastatic Colon Cancer***
>
> ***—Data Reported at the 2010 ASCO GI Cancers Symposium Demonstrate a Statistically Significant Improvement in Both Time to Tumor Progression and Overall Survival in the Perifosine + Capecitabine Arm Versus Placebo + Capecitabine Arm* -- Conference Call to Discuss Data to be Held on Thursday, January 28th at 9am EST**

NEW YORK, Jan 25, 2010 /PRNewswire via COMTEX/ -- Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX) yesterday reported updated results on the clinical activity of KRX-0401 (perifosine), the Company's PI3K/Akt pathway inhibitor for cancer, in combination with capecitabine (Xeloda®) as a treatment for advanced, metastatic colon cancer. Abstract #447, entitled, "Randomized phase II study of perifosine in combination with capecitabine (P-CAP) versus capecitabine plus placebo (CAP) in patients with second- or third-line metastatic colon cancer (mCRC): Updated results," was presented yesterday in a poster during the 2010 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium, held in Orlando, Florida.

STUDY DESIGN:

In this randomized, double-blind, placebo controlled study conducted at 11 centers across the United States, heavily pre-treated patients with second- or third-line metastatic colon cancer were randomized to receive capecitabine (a chemotherapy used in advanced metastatic colon cancer which is marketed by Roche as Xeloda®) at 825 mg/m2 BID (total daily dose of 1650 mg/m2) on days 1 - 14 every 21 days plus either perifosine or placebo at 50 mg daily. The study enrolled a total of 38 patients, 34 of which were third-line or greater. Of the 38 patients enrolled, 35 patients were evaluable for response (20 patients on the perifosine + capecitabine arm and 15 patients on the placebo + capecitabine arm). Three patients on the placebo + capecitabine arm were not evaluable for response (2 patients were unevaluable due to toxicity (days 14, 46) and 1 was unevaluable due to a new malignancy on day 6). All patients in the perifosine + capecitabine arm were evaluable for response.

The patients in the study were heavily pre-treated, with the arms well-balanced in terms of prior treatment regimens. The median number of prior treatment regimens for all 38 patients was two, with prior treatment regimens for the P-CAP arm versus CAP arm shown in the table below. Notably, all of the patients (with the exception of one CAP arm patient) had been treated with FOLFIRI and/or FOLFOX, almost 80% treated with Avastin®, and half treated with an EGFR antibody:

Prior RX	**P-CAP (n=20)**	**CAP (n=18)**	**All Patients (n=38)**
FOLFIRI	18 (90%)	16 (89%)	34 (89%)
FOLFOX	15 (75%)	13 (72%)	28 (74%)
FOLFIRI & FOLFOX	13 (65%)	12 (67%)	25 (66%)
Avastin®	15 (75%)	15 (83%)	30 (79%)
EGFR Antibody (1)	9 (45%)	10 (56%)	19 (50%)
5-FU Refractory Status	14 (70%)	13 (72%)	27 (71%)
Third Line or >	18 (90%)	16 (89%)	34 (89%)

(1) Prior treatment with Erbitux® and/or Vectibix®

The primary endpoint of this study was to measure Time to Progression (TTP). Overall Response Rate (ORR), defined as Complete Responses (CR) + Partial Responses (PR) by RECIST, and Overall Survival (OS) were measured as secondary endpoints.

STUDY RESULTS:

The P-CAP arm demonstrated a statistically significant advantage for TTP and OS, as well as for the percentage of patients achieving Stable Disease lasting 12 or more weeks (SD) or better, as compared to the CAP arm. The P-CAP arm demonstrated a greater than 60% improvement in OS, a more than doubling of median TTP, and almost a doubling of the percentage of patients achieving SD or better. In addition, the ORR was 20% (including one CR, and durable responses) in the P-CAP arm versus 7% in the CAP arm. The updated efficacy results for all evaluable patients are as follows:

Group	**n**	**ORR % CR / PR (Duration of Response)**	**Greater than or equal to SD (min 12 wks) n (%) p=0.036**	**Median TTP Weeks p=0.0012**	**Median OS* Months p=0.0136**
P-CAP	20	20% 1 CR (34 mos -ongoing) 3 PR (21, 19, 11 mos)	15 (75%)	28 [95% CI (12-48)]	18 [95% CI (10.8-25.7)]
CAP	15	7% 1 PR (7 mos)	6 (40%)	11 [95% CI (9-15.9)]	11 [95% CI (5.3-16.9)]

*Survival is calculated from date of randomization until the date of death from any cause, whether or not additional therapies were received after removal from treatment.
NOTE: Kaplan-Meier method used to calculate both TTP and OS. In addition, TTP and Progression Free Survival (PFS) are identical for all patients in the study.

Of notable interest, and for the first time presented, were data showing a highly statistically significant benefit in median OS (more than a doubling) and TTP for the subset of patients who were refractory to a 5-FU (Fluorouracil) chemotherapy-based treatment regimen. 5-FU is a core component of the standard of care FOLFIRI and FOLFOX regimens, and capecitabine is a 5-FU pro-drug. These results are shown below:

Group	5-FU Ref n (%)	Greater than or equal to SD (min 12 wks) n (%) p=0.066	Median TTP Weeks p=0.0004	Median OS Months p=0.0088
P-CAP	14 (70%)	1 PR / 8 SD (64%)	18 [95% CI (12-36)]	15.3 [95% CI (8.4-26)]
CAP	11 (73%)	0 PR / 3 SD (27%)	10 [95% CI (6.6-11)]	6.8 [95% CI (4.8-11.7)]

All patients were evaluable for safety. The P-CAP combination was well-tolerated with Grade 3 and 4 adverse events of > 10% incidence for the P-CAP arm versus CAP arm as follows: anemia (15% vs. 0%), fatigue (0% vs. 11%), abdominal pain (5% vs. 11%), and hand-foot syndrome (30% vs. 0%). Of note, incidence of Grade 1 and 2 hand-foot syndrome was similar in both the P-CAP and CAP arms (25% vs. 22%, respectively). Hand-foot syndrome is a reported adverse event with capecitabine monotherapy. Patients who remained on treatment longer in the Phase 2 study had a greater chance to develop hand-foot syndrome as illustrated by a median time to onset of Grade 3 and 4 hand-foot syndrome in the P-CAP arm of 19 weeks.

Commenting on the data, Dr. Cathy Eng, Associate Medical Director for Colorectal Cancer at MD Anderson Cancer Center in Houston, Texas, stated, "This randomized Phase 2 trial demonstrates the very promising activity of perifosine (an oral Akt pathway inhibitor) for response, PFS, and OS in the care of previously treated, advanced colorectal cancer. Akt is downstream from the EGFR receptor and may have a role also in KRAS mutant tumor types. Preclinical data suggest that the Akt pathway inhibitors may be of benefit not only with chemotherapy but also in combination with other biologic agents. Perifosine is definitely worthy of further analysis and should be pursued in a Phase 3 trial in this indication."

Dr. Paulo Hoff, Professor of Medicine and Chairman of Medical Oncology at the University of Sao Paulo, Brazil, and the lead investigator for the capecitabine (Xeloda®) Phase 3 approval study stated, "The data we see in this study for the capecitabine alone group is very much in line with expectation and, therefore, the combination data of perifosine plus capecitabine appears very compelling. It seems that the inhibition of Akt and other pathways by perifosine modulates the activity of capecitabine. What is of particular interest to me is the TTP and OS data for the 5-FU refractory patients, which holds great promise, and I urge the company to move forward into Phase 3."

Ron Bentsur, Chief Executive Officer of Keryx, commented "We are extremely excited by the data. ***It has been several years since any drug candidate has shown a robust advantage across all key efficacy parameters in such an advanced metastatic colorectal cancer patient population, especially a highly statistically significant improvement in survival.*** While we will need to confirm these results in a Phase 3 setting, we are excited at the opportunity to potentially provide a substantial improvement of care to a very advanced patient population which has failed some of the biggest blockbuster cancer

> drugs, such as Avastin® and Erbitux®." Mr. Bentsur added, "We are eager to finalize the design of a Phase 3 protocol in metastatic colorectal cancer within the next 3 months, in consultation with the FDA, and to commence the Phase 3 study as soon as practicable thereafter."

66. The aforementioned statements in ¶ 65 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups.

Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

67. On a January 28, 2010 conference call discussing the results of the Phase 2 study, Defendant Bentsur stated, in relevant part, the following:

> We are very excited about the colon data seen to date and as a result, we do plan to move forward aggressively in this indication.
>
> I will now very briefly describe the Phase 2 data and summarize the data presented. ***This Phase 2 was a randomized, placebo-controlled, double-blind study looking at second or third line metastatic colon cancer patients and comparing two arms of treatment -- perifosine plus capecitabine versus placebo plus capecitabine***. I'm not going to rehash every statistic that was included in the press release and I do encourage you to review the press release if you haven't already done so but I'll highlight some of the key mentions with regard to the study.
>
> ***There were 38 patients enrolled, 34 of which were third line or greater than third line; so a very sick patient population***. Very importantly, baseline characteristics were very similar; in fact, almost identical between the two arms with regard to age, median prior lines of therapy, prior therapies received and percentage of patients with 5-FU-refractory status; giving you a very strong set of the balance between the two arms and just how sick this patient population was, having failed most of these therapies.
>
> The primary endpoint for this study was to measure time to tumor progression, overall response rate defined as complete responses plus partial responses by resist and overall survival were measured as secondary endpoints. We're very excited about the ***dramatic advantages that we saw across all key efficacy parameters, in particular the time to***

tumor progression and survival data for the overall population and the 5-FU-refractory patients in this study.

68. The aforementioned statements in ¶ 67 were false and/or materially misleading when made

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance

of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

69. On February 3, 2010, Keryx announced a Special Protocol Assessment Agreement with the FDA to conduct a Phase 3 trial of perifosine in the treatment of patients with refractory metastatic colorectal cancer. The press release stated, in relevant part, the following:

> **Keryx Biopharmaceuticals Announces Special Protocol Assessment Agreement with FDA for Phase 3 Trial of KRX-0401 (Perifosine) in the Treatment of Patients with Refractory Metastatic Colorectal Cancer**
>
> **Phase 3 X-PECT Trial (Xeloda®+ Perifosine Evaluation in Colorectal cancer Treatment) to be led by Dr. Johanna Bendell, Director, GI Oncology Research, Sarah Cannon Research Institute**
>
> NEW YORK, Feb 03, 2010 /PRNewswire via COMTEX/ -- Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX) announced today that it has reached agreement with the U.S. Food and Drug Administration (FDA) regarding a Special Protocol Assessment (SPA) on the design of a Phase 3 trial for its PI3K/Akt pathway inhibitor, KRX-0401 (perifosine), in patients with refractory metastatic colorectal cancer. The SPA provides agreement that the Phase 3 study design adequately addresses objectives in support of a regulatory submission.
>
> PHASE 3 TRIAL DESIGN:
>
> The Phase 3 X-PECT *(**X**eloda® + **P**erifosine **E**valuation in **C**olorectal cancer **T**reatment)* trial will be a randomized (1:1), double-blind trial comparing the efficacy and safety of perifosine + capecitabine (capecitabine is a chemotherapy marketed by Roche as Xeloda®) vs. placebo + capecitabine in approximately 430 patients with refractory

metastatic colorectal cancer. Patients must have failed available therapy including 5-fluorouracil (5-FU), oxaliplatin (Eloxatin®), irinotecan, bevacizumab (Avastin®) and, if K-Ras wild-type (WT), failed therapy with prior cetuximab (Erbitux®) or panitumumab (Vectibix®). For oxaliplatin-based therapy, failure of therapy will also include patients who discontinued due to toxicity. The primary endpoint is overall survival (OS), with secondary endpoints including overall response rate (ORR: complete responses + partial responses), progression-free survival (PFS) and safety. The median OS for the X-PECT study's targeted patient population, that has failed prior therapies as described above, is approximately 5 months. The X-PECT study will be powered at 90% to detect a statistically significant difference in OS, with an assumed median OS for the control arm of 5-6 months and 7-8 months for the perifosine arm. Approximately 360 events of death will trigger the un-blinding of the study.

Approximately 40 to 50 U.S. sites will participate in the study. ***The study is expected to begin in 2Q 2010, and enrollment is expected to take approximately 12 months, with study completion expected in 2H 2011***. . . .

. . . .

Dr. Johanna Bendell, commented, "More active agents are needed to improve survival for patients with metastatic colorectal cancer. We are very excited about this Phase 3 trial, which is based on the encouraging randomized Phase 2 data that demonstrated an improvement in overall survival and time to progression using perifosine plus capecitabine over placebo plus capecitabine in patients with metastatic colorectal cancer. As such, we are moving forward with the randomized Phase 3 X-PECT trial, and we hope to continue to see these improvements in patient outcomes."

Dr. Cathy Eng, added, "The updated Phase 2 data presented at the 2010 Gastrointestinal Cancers Symposium in Orlando, Florida, demonstrated promising activity and outcomes for heavily pretreated metastatic colorectal cancer patients treated with the combination of perifosine plus capecitabine and provided heightened awareness of the potential therapeutic role of an oral PI3K/Akt pathway inhibitor. The Phase 3 X-PECT trial will provide a greatly needed opportunity for our patients that would normally have very limited treatment options."

Ron Bentsur, Chief Executive Officer of Keryx, stated, "This SPA represents another important milestone for the company, and we wish to thank the FDA for their guidance and support in this process. We also wish to thank the Phase 2 investigators and the experts that helped us obtain this SPA. ***We are very encouraged by the colon Phase 2 data that was recently announced, which showed a statistically significant survival advantage in a refractory metastatic patient population***." Mr. Bentsur continued, "This is a very exciting time for Keryx, as we have transitioned into a late-stage development company with two drugs in Phase 3 pursuing three indications under SPAs. We eagerly await the commencement of the X-PECT study within a few months."

70. The aforementioned statements in ¶ 69 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

d. Defendants knew or recklessly disregarded the fact that the Phase 3 X-

PECT study would (or could) be completed later than the second half of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

71. On February 9, 2010, Defendant Bentsur made a presentation at the Biotech Industry Organization CEO & Investor Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> Let me talk a little bit about the metastatic colon Phase 2 data that we saw, and why we're so excited about this particular indication. ***So, what we did in this Phase 2 study was we took second or third line metastatic colon cancer patients***. In fact, with the exception of four patients, all of the patients in this Phase 2 were third line or worse. ***And this was a double blind, randomized, placebo controlled study, essentially looking at two arms: Perifosine plus capecitabine, which is standard of care in third line***. It's also [] called Xeloda, that's the marketing name, the trade name. It's a chemotherapy that's marketed by Roche.
>
> ***And the other arm was capecitabine plus placebo***. So, essentially we had an active control group in this study. ***There were 38 patients that were enrolled into the study; 35 were evaluable for data.*** By the way, the three patients that dropped out were all from the placebo group. And this slide here really goes to demonstrate the fact that the two arms were very evenly balanced going into the study.
>
> So the baseline characteristics, in the next slide you will see, which is the pretreatment, was very well-balanced between the two arms. You can see that the median age was about the same, the median prior lines of therapy and also the 5-FU refractory status. That's very important because capecitabine is a 5-FU pro-drug. So it's very important for the doctors that we showed this data to understand whether there was balance between the arms in terms of the 5-FU refractory status of these patients.
>
> And also the pretreatments of these patients, as you can see this is kind of a laundry list of everything that's available for these patients, FOLFOX, FOLFIRI, Avastin, Erbitux, panitumumab, you go down the list. You can – first of all you can see that the two arms are very well-balanced and this gives you a sense as to just how refractory these patients were coming into the study.
>
> Let me talk a little bit about the response rate information that was generated in this study. I know that this is a little bit of a busy slide, but it's important to highlight. So we

actually had 20 patients evaluable in the placebo plus capecitabine – in the perifosine plus capecitabine arm versus 15 in the capecitabine plus placebo arm.

We actually had one CR and three PRs over here and only one PR over here and the duration of the responses also appeared to be a lot more robust. And if you include the cases of stable disease as you move down in the columns, cases versus five, you add all that up, you get to ***a clinical benefit rate, which is stable disease or better of 15 patients versus 6 or 75% versus 40; that happened to be statistically significant as well.***

So you can already see a delta forming in so far as response rate is concerned. Looking down at the 5-FU refractory population, that was about two-thirds of the patients in the study. You can see that the perifosine/capecitabine arm had one PR versus nothing down in the capecitabine plus placebo arm as expected.

But we had there also, if you look at the category of stable disease, eight cases versus three and you add all that up, you get to a stable disease or better rate of nine versus three or 64% versus 27. Again, there appears to be a pretty big delta there. Looking on at time-to-tumor progression, if you look on the left side, you see the time-to-tumor progression numbers for both, for all the evaluable patients, all 35 of them. So 28 weeks in the perifosine plus capecitabine arm versus 11 weeks for the perifosine – for the capecitabine plus placebo arm.

And if looking at the 5-FU refractory patients on the right side, again, you see that delta continuing 18 weeks versus 10. And moving on to survival, which is the most important parameter, obviously, looking on the left side at the – all evaluable patients, you see almost a doubling of survival, 18 months versus 11. And if you look at the 5-FU refractory patients, in fact, it's about a doubling of survival, 15 versus 6.8.

. . . .

In terms of the Phase 3 schematic, this is the Special Protocol Assessment that was finalized with the FDA about 10 days ago. We're going to randomize 430 patients. They will go into one of two arms, very similar to the Phase 2, capecitabine plus placebo versus capecitabine plus perifosine. This will be an event driven study. So, 360 events of death in this case will trigger the unblinding of the study. Our primary end point is overall survival and we need to show a statically significant difference in survival.

We expect that enrollment time will take about 12 months for this study, so net-net ***we do expect to complete this study in the second half of 2011***.

72. The aforementioned statements in ¶ 71 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2

protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the second half of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

73. On March 11, 2010, Defendant Bentsur made a presentation at the Cowen and Company 30th Annual Health Care Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> Let me talk a little bit about the colon Phase II study that was recently completed, and this is really serving as the basis for us going into Phase III. ***And this was a randomized, double-blind Phase II study of perifosine plus capecitabine or Xeloda versus capecitabine plus placebo in second or third-line metastatic colon cancer patients***. In fact with the exception of four patients, all of the patients were third-line or worse in this study.
>
> ***38 patients were enrolled, 35 were invaluable for efficacy, the three that dropped out were all from the placebo group***. And if you look at the patient demographics and some baseline characteristics coming into the study, you will find that across all the key parameters, the two arms were very evenly divided, the capecitabine plus perifosine versus capecitabine plus placebo arms were very evenly divided. There is no imbalance going into the study, and that's obviously very important in a randomized study.
>
> So in terms of the median age, that was about the same at 65 or so, and the median prior lines of therapy for each group was about 2.6, and the status, the 5-FU refractory status of the patients in each arm was also a very important parameter, because capecitabine is a 5-FU pro-drug. So that was a very important parameter for us to assess and also to all the

doctors that we spoke to, and in fact you can see that it was evenly divided between the two groups.

And moving on to the prior treatments, more specifically for FOLFOX, FOLFIRI, Avastin, Erbitux, Vectibix, et cetera. You can see that if you compare the two arms, there is almost a clone of one another, there is no imbalance and the two arms were very evenly balanced coming into the study.

The next slide talks about the response rate information that was generated, and if you look in the upper bracket, 20 patients were invaluable for efficacy in the perifosine plus capecitabine arm versus 15 patients in the capecitabine plus placebo arm. ***And you can see in the perifosine plus capecitabine arm, one CR and three PRs versus only one PR in the capecitabine plus placebo arm, so that alone is a significant difference between the two Rs, and also it's very interesting to see the duration of the responses.***

You can see, in the perifosine plus capecitabine arm, duration of responses of 34 months, 21, 19, 11, versus a seven month duration for the one PR in the capecitabine plus placebo arm. So again, there appears to be the responses, also appear to be more robust in terms of duration. If you include the cases of stable disease, 11 cases versus five, you get to a clinical benefit rate which is stable disease or better of 15 versus six, or 75% versus 40, that was a statistically significant result.

And then if you look at the 5-FU refractory patients, which were about two-thirds of the patients in this study, you will see that there was one PR in the perifosine plus capecitabine arm versus nothing in the capecitabine plus placebo arm. But very interestingly is the cases of stable disease, eight versus three for a clinical benefit rate which is stable disease or better of nine versus three or 64% versus 27 in the 5-FU refractory patient population. So, it does appear that the responses in the stable diseases incidence is certainly in the favor of the perifosine plus capecitabine arm.

Moving on to Time to Tumor Progression, the Median TTP for all of valuable patients in the perifosine plus capecitabine arm was 28 weeks versus 11 weeks for the capecitabine placebo arm that was statistically significant, almost a tripling of the Time to Tumor Progression. And then if you look at the Time to Tumor Progression for the 5-FU refractory population, it's 18 weeks versus 10, also statistically significant.

And moving on finally to survival, ***which is arguably the most important parameter***, you will see that ***for the overall patient population, the median overall survival for the perifosine capecitabine arm was 18 months versus 11 months for the capecitabine placebo arm. And on to the right side, the 5-FU refractory patient population, it was 15 months versus about 6.8 months, so more than a doubling of median survival in the 5-FU refractory population.***

74. The aforementioned statements in ¶ 73 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be

approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

75. On March 16, 2010, Defendant Bentsur made a presentation at the Roth Capital Partners OC Growth Stock Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> Let me talk a little bit about the Phase 2 data in metastatic colon. The data that was generated last year first came out at ASCO of 2009. And then there was an update presentation recently at GI ASCO Meeting in late January. ***And this was a randomized, double-blind, placebo-controlled study looking at second- or third-line metastatic colon cancer patients***. In fact, with the exception of four patients, all of the patients in the study were third line or worse. And what we did in this study was we randomized these patients into one of two arms; either perifosine, which is our drug plus capecitabine/Xeloda, versus capecitabine plus placebo.
>
> ***In terms of baseline characteristics and a few other parameters, patient demographics; 38 patients were enrolled into the study 35 were evaluable for efficacy***. The three that dropped out were all from the placebo group, incidentally. Not a single patient dropped out from the perifosine arm.
>
> And here, what you see is basically a breakdown of some key parameters. We wanted to make sure that the study was not imbalanced; that in fact the two arms were very evenly matched going into the study. So you can see median age, median prior lines of therapy. And this is also a very important parameter. Here is 5-FU refractory status of these patients. The reason that's important is because capecitabine is 5-FU pro-drug. So it's important to understand whether the two arms are balanced insofar as 5-FU refractory status is concerned. And you can see that in fact they were almost evenly matched.
>
> Looking at other pre-treatments. FOLFOX, FOLFIRI, Avastin, Erbitux; all these names that many of you are familiar with. You can see again that the two arms are very evenly matched. In fact, they're almost identical. So clearly, there was no imbalance going into the study in favor of one arm versus the other.
>
> This is the response rate information that was generated in the study. This is a bit of a busy slide, but there's a lot of important information here. ***This is for the overall patient***

population; all evaluable patients, 35. You can see the perifosine plus capecitabine arm, 20 patients versus 15 in the capecitabine/placebo arm. And in the perifosine arm, there was actually one CR, complete responder, and three partial responders versus only one PR down here in the capecitabine/placebo arm.

And you can see the duration of the responses also appears to be a lot more robust, measured in some cases north of two years versus seven months for the one PR down here. And then if you include the cases of stable disease, 11 versus five, you get to a Clinical Benefit Rate, which is stable disease or better, of 15 cases versus six or 75% versus 40. ***And that was also a statistically-significant result.***

Looking at the 5-FU refractory patient population, about two-thirds of the patients in the study, that subset that came in refractory to prior 5-FU treatment; you can see one PR here. That's the one person with a 19-month response over here. But look at the number of stable disease; eight versus three for a Clinical Benefit Rate, again which is defined as stable disease or better of nine versus three; 64% versus 27.

Moving on to Time to Tumor Progression, which was the primary endpoint for the study. Looking at all evaluable patients; we're looking at 28 weeks for the perifosine/capecitabine arm versus 11 weeks for the capecitabine/placebo arm. ***And that difference was statistically significant.***

Moving on to the 5-FU refractory patient population. The Time to Tumor Progression figures there were 18 weeks versus 10; again highly statistically significant. And finally the most important parameter is of course survival, and there was a dramatic difference in survival. Looking at the overall patient population, 18 months versus 11; statistically-significant score. And looking at the 5-FU refractory patient population, more than a doubling of survival, about 15 months versus about six and-a-half months for a statistically-significant result as well.

So obviously, we're very excited about this program. And we showed this to the FDA. And we came up with this schematic for the Phase 3 trial, which is set to begin as I said within the next two months or so. And this is essentially the schematic under the Special Protocol Assessment that was locked up with the SPA, and with the FDA under the SPA. So we're looking at third-line patients or worse. We're going to enroll 430 patients into the study. They're going to be randomized into one of two arms; either perifosine plus capecitabine versus capecitabine plus placebo. So essentially, this is pretty much a mimic of the 5-FU refractory patient population that was in our Phase 2. And 360 events of death will trigger the unblinding of the study. And the primary endpoint is overall survival. We need to show a statistically significant difference in survival.

76. The aforementioned statements in ¶ 75 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2

protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

77. On March 25, 2010, the Company filed its annual report on Form 10-K ("2009 10-K") with the SEC and made the following representations:

Colorectal Cancer Clinical Data

> ***In January 2010, we announced updated data from a randomized, multi-center, double-blind, placebo-controlled, Phase 2 study of KRX-0401 (perifosine) in combination with capecitabine (Xeloda®) versus capecitabine plus placebo in patients with second- or third-line metastatic colon cancer***. The data was presented at the 2010 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium, held in Orlando, Florida in a poster entitled, "Randomized phase II study of perifosine in combination with capecitabine (P-CAP) versus capecitabine plus placebo (CAP) in patients with second- or third-line metastatic colon cancer (mCRC): Updated results." The data was initially presented at the ASCO 45th Annual Meeting in June 2009.
>
> ***In this randomized, double-blind, placebo controlled study conducted at 11 centers across the United States, heavily pre-treated patients with second- or third-line metastatic colon cancer were randomized to receive capecitabine (a chemotherapy used in advanced metastatic colon cancer which is marketed by Roche as Xeloda®) at 825 mg/m^2 BID (total daily dose of 1650 mg/m^2) on days 1 – 14 every 21 days plus either placebo or perifosine at 50 mg daily. The study enrolled a total of 38 patients, 34 of which were third-line or greater***. ***Of the 38 patients enrolled, 35 patients were evaluable for response (20 patients on the perifosine + capecitabine arm and 15 patients on the placebo + capecitabine arm)***. Three patients on the placebo + capecitabine arm were not evaluable for response (2 patients were non-evaluable due to toxicity (days 14, 46) and 1 was non-evaluable due to a new malignancy on day 6). All patients in the perifosine + capecitabine arm were evaluable for response. The median number of prior treatment regimens for all 38 patients was two, with prior treatment regimens for the P-CAP arm versus CAP arm shown in the table below.

Prior Treatments	P-CAP (n=20)	CAP (n=18)	All Patients (n=38)
FOLFIRI	18 (90%)	16 (89%)	34 (89%)
FOLFOX	15 (75%)	13 (72%)	28 (74%)
FOLFIRI & FOLFOX	13 (65%)	12 (67%)	25 (66%)
Avastin®	15 (75%)	15 (83%)	30 (79%)
EGFR Antibody (1)	9 (45%)	10 (56%)	19 (50%)
5-FU Refractory Status	14 (70%)	13 (72%)	27 (71%)
Third Line or >	18 (90%)	16 (89%)	34 (89%)

(1) Prior treatment with Erbitux® and/or Vectibix®

The primary endpoint of this study was to measure Time to Progression (TTP). Overall Response Rate (ORR), defined as Complete Responses (CR) + Partial Responses (PR) by RECIST, Overall Survival (OS) and safety were measured as secondary endpoints.

The reported efficacy results for all evaluable patients were as follows:

Group	n	ORR % CR/PR (Duration of Response)	> SD (min 12 wks) n (%)	Median TTP Weeks	Median OS* Months
P-CAP	20	20% 1 CR (34 mos-ongoing) 3 PR (21, 19, 11 mos)	15 (75%)	28 [95% CI (12-48)]	18 [95% CI (10.8-25.7)]
CAP	15	7% 1 PR (7 mos)	6 (40%)	11 [95% CI (9-15.9)]	11 [95% CI (5.3-16.9)]
p-value			***p=0.036***	***p=0.0012***	***P=0.0136***

*Survival is calculated from date of randomization until the date of death from any cause, whether or not additional therapies were received after removal from treatment.

NOTE: Kaplan-Meier method used to calculate both TTP and OS. In addition, TTP and Progression Free Survival (PFS) are identical for all patients in the study.

Results for the subset of patients who were refractory to a 5-FU (Fluorouracil) chemotherapy-based treatment regimen are shown in the table below. 5-FU is a core component of the standard of care FOLFIRI and FOLFOX regimens, and capecitabine is a 5-FU pro-drug.

Group	5-FU Ref (n%)	> SD (min 12 wks) n (%)	Median TTP Weeks	Median OS Months
P-CAP	14 (70%)	1 PR / 8 SD (64%)	18 [95% CI (12-36)]	15.3 [95% CI (8.4-26)]
CAP	11 (73%)	0 PR / 3 SD (27%)	10 [95% CI (6.6-11)]	6.8 [95% CI (4.8-11.7)]
p-value		***p=0.066***	***p=0.0004***	***p=0.0088***

> All 38 patients were evaluable for safety. The P-CAP combination was well-tolerated with Grade 3 and 4 adverse events of > 10% incidence for the P-CAP arm versus CAP arm as follows: anemia (15% vs. 0%), fatigue (0% vs. 11%), abdominal pain (5% vs. 11%), and hand-foot syndrome (30% vs. 0%). Of note, incidence of Grade 1 and 2 hand-foot syndrome was similar in both the P-CAP and CAP arms (25% vs. 22%, respectively). Hand-foot syndrome is a reported adverse event with capecitabine monotherapy. Patients who remained on treatment longer in the Phase 2 study had a greater chance to develop hand-foot syndrome as illustrated by a median time to onset of Grade 3 and 4 hand-foot syndrome in the P-CAP arm of 19 weeks.

78. The aforementioned statements in ¶ 77 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for

the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

79. The 2009 10-K was certified by Defendant Bentsur, who respectively attested to the following:

> 1. I have reviewed this annual report on Form 10-K of Keryx Biopharmaceuticals, Inc.;
>
> 2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
>
> 3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
>
> 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

80. Additionally, Defendant Bentsur certified under Section 906 of the Sarbanes-Oxley Act of 2002 that the "information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

81. Also on March 25, 2010, in a conference call discussing the results for Q4 2009, Defendant Bentsur stated, in relevant part, the following:

> On our third quarter call, we mentioned that we had become engaged in discussions with the FDA for a Phase 3 program for perifosine for the treatment of metastatic colorectal cancer. About two months ago, we announced that we had reached a mutual agreement with the FDA on an SPA for the Phase 3 study of perifosine in the treatment of metastatic colorectal cancer.
>
> The designer of Phase 3 study, as agreed upon with the FDA and pursuant to our SPA, is as follows: we're calling this study the Phase 3 X-PECT study, Xeloda plus perifosine evaluation in colorectal cancer treatment. This will be a randomized double-blind study comparing the efficacy and safety of perifosine plus capecitabine versus – plus placebo plus capecitabine. As a reminder, capecitabine is a chemotherapy marketed by Roche under the trade name Xeloda.
>
> We are going to enroll approximately 430 patients with refractory metastatic colorectal cancer into the study. The primary endpoint is overall survival with secondary endpoints including overall response rates, progression-free survival and safety. The median overall survival for the X-PECT study's targeted patient population that has failed all available therapies is approximately five months, approximately 40 to 50 sites will participate in the study.
>
> The study is expected to begin in the second quarter of this year with ***study completion expected in the second half of 2011.*** Dr. Johanna Bendell, Director of GI Oncology Research for the Sarah Cannon Research Institute in Nashville, Tennessee will lead the Phase 3 investigational team that also includes Dr. Cathy Eng, Associate Medical Director of the Colorectal Center at the MD Anderson Cancer Center in Houston, Texas.
>
> In January, the company held a conference call to discuss the completed Phase 2 study, which was presented at the ASCO GI Symposium and which is serving us the basis for our planned Phase 3 study described just a moment ago. Since we already discussed the data from the Phase 2 study on the January call that we had, I'll just quickly summarize the data from this randomized double-blind Phase 2 study of perifosine plus Xeloda versus Xeloda plus placebo in patients with metastatic colorectal cancer.
>
> ***Across all key efficacy parameters, the perifosine plus Xeloda arm was superior compared to the Xeloda plus placebo arm. In fact, the time to tumor progression and most importantly the survival advantages observed were robust, yielding highly statistically significant differences between the two arms in favor of the perifosine arm***.
>
> ***We are extremely excited by this result. It has been several years since any drug candidate has shown a robust advantage across all key efficacy parameters in such an advanced metastatic colorectal cancer patient population, especially a highly statistically significant improvement in survival***.

. . . .

> So to recap with a view towards an exciting and busy 2010, shareholders can look forward to the following upcoming milestones. For perifosine, continued ongoing recruitment into the multiple myeloma Phase 3 study being conducted pursuant to the Special Protocol Assessment with data expected in the second half of 2011.
>
> Commencement of the Phase III metastatic colon cancer study, with anticipated start in the second quarter, ***data also expected in the second half of 2011***; as well as data presentations at some of the key medical conferences throughout the year.

82. The aforementioned statements in ¶ 81 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

d. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the second half of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

83. On April 5, 2010, Keryx announced that the Phase 3 X-PECT trial received FDA fast track designation.

84. On April 8, 2010, Keryx initiated the Phase 3 X-PECT trial. The press release announcing the launch of the study stated, in relevant part, the following:

> **Keryx Biopharmaceuticals, Inc. Initiates Phase 3 Registration Trial of KRX-0401 (Perifosine) for Treatment of Patients with Refractory Advanced Colorectal Cancer Phase 3 X-PECT Trial (Xeloda® + Perifosine Evaluation in Colorectal cancer Treatment) being conducted pursuant to Special Protocol Assessment with Food and Drug Administration**
>
> NEW YORK, April 8, 2010 /PRNewswire via COMTEX/ --Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX) announced today the initiation of a Phase 3 registration clinical trial for KRX-0401 (perifosine), the Company's novel, potentially first-in-class, oral anti-cancer agent that inhibits Akt activation in the phosphoinositide 3-kinase (PI3K) pathway, for the treatment of patients with refractory advanced colorectal cancer.
>
> The Phase 3 trial, entitled the "X-PECT" *(**X**eloda® + **P**erifosine **E**valuation in **C**olorectal cancer **T**reatment)* trial, is a randomized (1:1), double-blind trial comparing the efficacy and safety of perifosine + capecitabine vs. placebo + capecitabine in approximately 430 patients with refractory advanced colorectal cancer. Patients must have failed available

> therapy including 5-fluorouracil (5-FU), oxaliplatin (Eloxatin®), irinotecan (Camptosar®), bevacizumab (Avastin®) and, if KRAS wild-type, failed therapy with prior cetuximab (Erbitux®) or panitumumab (Vectibix®). For oxaliplatin-based therapy, failure of therapy will also include patients who discontinued due to toxicity. The primary endpoint for this study is overall survival, with secondary endpoints including overall response rate, progression-free survival and safety. This trial is being conducted pursuant to a Special Protocol Assessment (SPA) with the Food and Drug Administration. Perifosine has also been granted Fast Track designation for the treatment of refractory advanced colorectal cancer.
>
> . . . .
>
> Approximately 40 to 50 U.S. sites will participate in the study. Enrollment is expected to take approximately 12 to 14 months, with ***study completion expected in the second half of 2011.***
>
> . . . .
>
> Ron Bentsur, CEO of Keryx Biopharmaceuticals, commented: "Keryx is committed to developing perifosine as a treatment that will provide meaningful therapeutic value for patients living with refractory advanced colorectal cancer. ***The Phase 2 trial conducted in this setting provides strong rationale for the benefit of the perifosine/capecitabine combination in the treatment of advanced refractory colorectal cancer*** and we are extremely excited to initiate this Phase 3 registration trial, pursuant to our SPA, with the goal of potentially having the drug on the market for this indication by mid-2012."

85. The aforementioned statements in ¶ 84 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

d. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the second half of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

86. On a May 11, 2010 conference call discussing the results for Q1 2010, Defendant Bentsur stated, in relevant part, the following:

> [L]ast month, we announced the initiation of our Phase 3 study for advanced refractory colorectal cancer.
>
> The Phase 3 X-PECT trial, which stands for Xeloda+Perifosine Evaluation in Colorectal cancer Treatment, is being laid by Dr. Johanna Bendell, Director of GI Oncology Research for the Sarah Cannon Research Institute.

> Keryx is committed to developing perifosine as a treatment that will provide meaningful therapeutic value for patients living with refractory advanced cancer and for which there are very few treatment options.
>
> We are pleased with the rate of enrollment into each of these ongoing Phase 3 studies, and we continue to believe that those studies, the Phase 3 X-PECT study for advanced refractory colorectal cancer and the multiple myeloma Phase 3 study, will be completed with ***data available in the second half of 2011*** and that perifosine could potentially be on the market by mid 2012.

87. The aforementioned statements in ¶ 86 were false and/or materially misleading when made because Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the second half of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

88. On May 17, 2010, Defendant Bentsur made a presentation at the Rodman & Renshaw Global Healthcare Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> ***Let me talk about the dataset that many people believe is the most exciting dataset that we have and this is the randomized double-blind Phase II study that was conducted in metastatic colon. Patients came in; it was a double-blind study. They were randomized in the one of two arms, either perifosine plus capecitabine (Xeloda) or capecitabine plus placebo***. And these were all second or third line metastatic colon cancer patients. In fact, with the exception of four patients, all of them were third line or worse. And you'll see what I mean in a moment.
>
> . . . .
>
> And this is the breakdown by group in terms of just key base line characteristics, so you look at the capecitabine perifosine arm here, capecitabine plus placebo arm here. And you can see that by way of median age, median prior lines of therapies coming into the study, and very importantly the 5-FU refractory status of these patients.

All these parameters, the two groups appear to be almost direct clones of one another. There are certainly no discrepancies between the two arms. This is a very important parameter here. The 5-FU refractory status of the patients and that is because capecitabine is a 5-FU pro-drug. So obviously the doctors, and so did we, we wanted to make sure that there were no distortions between the two arms insofar as that parameter is concerned.

Also very importantly is the prior treatments of the patients coming into the study and you can see the two arms again. And they're all – the two arms are almost identical in terms of the treatment experiences that these patients had before coming in – FOLFIRI, FOLFOX, Avastin, Erbitux, Vectibix which is another EGFR inhibitor, the two arms in a nutshell were very well balanced. So there were no major discrepancies between the two arms coming into the study.

This is a bit of busy slide, but it's very important. This is the response rate information that was generated and we're looking at all evaluable patients in the 5-FU refractory sub-patient population, which was about two-thirds of the patients in the study. Looking at all evaluable patients in the perifosine capecitabine arm here, 20 patients versus 15 capecitabine – the placebo arm.

We actually had one CR, complete responder, and three partial responders appear versus one partial responder down here. And you can see the duration of the responses versus the controlled group. The durations do appear to be a lot more robust, which is also a very good indicator.

In addition to that, you look at the cases of stable disease, 11 versus 5 and you get to what we call a clinical benefit rate of 15 versus 6 or 75% versus 40 and that was also statistically significant. Going down to the 5-FU refractory group, you can see that the stable disease or, better, the clinical benefit rate was 64 versus 27, again, a very clear advantage for the perifosine capecitabine arm versus capecitabine placebo.

Moving on to time to tumor progression, which was also the primary end point for this Phase II study, you can see immediately – the naked eye can immediately sense that there is a very strong divergence of the two curves. And if you look at the perifosine capecitabine arm, the median time to tumor progression was 28 weeks versus 11 weeks for the capecitabine placebo arm, more than a doubling of the time to tumor progression.

Moving on to 5-FU refractory patient population, 18 weeks versus 10, so almost a doubling of that parameter up for the 5-FU refractory patients, and both of these scores were statistically significant. The holy grail, of course, is to see a survival advantage and we, in fact, saw a survival advantage in this double-blind randomized study. And if you look at all evaluable patients, the median overall survival for the perifosine capecitabine arm was 18 months versus 11 months for the capecitabine placebo arm. Moving on to the 5-FU refractory patients, it was 15 months versus 6.8.

> So you can see that along all the key efficacy parameters that one looks at in an oncology study in a very, very sick patient population, ***we're seeing a consistent and robust advantage for perifosine as compared to the control group***.
>
> With that said, this is the schema for the Phase III study which is already underway. We're looking to enroll 430 patients, broken down into one of two arms. This is very much a replica of the Phase II. So the first arm will be capecitabine placebo; the treatment arm will be capecitabine perifosine. The primary endpoint is overall survival. We need to show statistically significant difference in overall survival and this will be an event-driven study, whereby 360 events of death in this case will trigger the unblinding of the study. ***We expect to generate data from the study in the second half of 2011.***

89. The aforementioned statements in ¶ 88 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the second half of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

90. On June 8, 2010, the Company issued a press release announcing the final results for the Phase 2 study. The press release stated, in relevant part, the following:

Keryx Reports Final Results of a Randomized, Double-Blind, Placebo-Controlled Phase 2 Study of KRX-0401 (Perifosine) in the Treatment of Advanced Metastatic Colorectal Cancer

Data Reported at 46th Annual ASCO Meeting Confirms a Statistically Significant Improvement in Both Time to Tumor Progression and Overall Survival in the Perifosine + Capecitabine Arm Versus Placebo + Capecitabine Arm

NEW YORK, June 8, 2010 /PRNewswire via COMTEX/ --Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX) today reported final results on the clinical activity of KRX-0401 (perifosine), the Company's oral anti-cancer agent that inhibits Akt activation in the phosphoinositide 3-kinase (PI3K) pathway, in combination with capecitabine (Xeloda®) as a treatment for advanced, metastatic colorectal cancer. Abstract #3531, entitled, "Final results of a randomized phase II study of perifosine in combination with capecitabine (P-CAP) versus capecitabine plus placebo (CAP) in patients with second- or third-line metastatic colorectal cancer (mCRC)," is being presented today in a poster discussion held during the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago.

STUDY DESIGN:

The patients in the study were heavily pre-treated, with the arms well-balanced in terms of prior treatment regimens. ***The prior treatment regimens for all 38 patients are shown in the table below***. Notably, all of the patients (with the exception of one CAP arm patient) had been treated with FOLFIRI and/or FOLFOX, almost 80% treated with Avastin®, and half treated with an EGFR antibody:

Prior RX	P-CAP (n=20)	CAP (n=18)	All Patients (n=38)
FOLFIRI	18 (90%)	16 (89%)	34 (89%)
FOLFOX	15 (75%)	13 (72%)	28 (74%)
FOLFIRI & FOLFOX	13 (65%)	12 (67%)	25 (66%)
Avastin®	15 (75%)	15 (83%)	30 (79%)
EGFR Antibody (1)	9 (45%)	10 (56%)	19 (50%)
5-FU Refractory Status	14 (70%)	13 (72%)	27 (71%)
Third Line or >	18 (90%)	16 (89%)	34 (89%)

(1) Prior treatment with Erbitux® and/or Vectibix®

The primary endpoint of this study was to measure Time to Progression (TTP). Overall Response Rate (ORR), defined as Complete Response (CR) + Partial Response (PR) by RECIST, and Overall Survival (OS) were measured as secondary endpoints.

STUDY RESULTS:

The P-CAP arm demonstrated a statistically significant advantage for TTP and OS, as well as for the percentage of patients achieving Stable Disease (SD) or better lasting 12

or more weeks, as compared to the CAP arm. The P-CAP arm demonstrated a greater than 60% improvement in OS, a more than doubling of median TTP, and almost a doubling of the percentage of patients achieving SD or better. In addition, the ORR was 20% (including one CR, and durable responses) in the P-CAP arm versus 7% in the CAP arm.

The final efficacy results are as follows:

ALL EVALUABLE PATIENTS (n=35):

Group	***n***	***CR n (%)***	***PR n (%)***	***Duration of Response***	***> SD (min 12 wks) n (%) p=0.036***
P-CAP	20	1 (5%)	3 (15%)	CR: 35m PR: 21, 19, 11 m	11 (55%)
CAP	15	0	1 (7%)	PR: 7m	5 (33%)

Group	***PD< 12 wks n (%)***	***Median TTP Wks p=0.0012***	***Median OS* p=0.0161***
P-CAP	5 (25%)	28 [95% CI (12-48)]	17.7 [95% CI (8.5-24.6)]
CAP	9 (60%)	11 [95% CI (9-15.9)]	10.9 [95% CI (5-16.9)]

*Survival is calculated from date of randomization until the date of death from any cause, whether or not additional therapies were received after removal from treatment.

Of notable interest were the patients who were previously refractory to a 5-FU based regimen. The P-CAP arm again demonstrated a statistically significant increase in both TTP and OS compared to the CAP arm. The final data is illustrated below:

5-FU REFRACTORY PATIENTS (n=25):

Group	***n (%)***	***PR n (%)***	***Duration of Response***	***> SD (min 12 wks) n (%) p=0.066***
P-CAP	14 (70%)	1 (7%)	19 m	8 (57%)
CAP	11 (73%)	0	-	3 (27%)

Group	***PD < 12 wks n (%)***	***Median TTP Wks P=0.0004***	***Median OS Months P=0.0112***
P-CAP	5 (36%)	18 [95% CI (12-36)]	15.1 [95% CI (7.3-22.3)]
CAP	8 (73%)	10 [95% CI (6.6-11)]	6.6 [95% CI (4.7-11.7)]

All 38 patients were evaluable for safety. The P-CAP combination was well-tolerated with Grade 3 and 4 adverse events of > 10% incidence for the P-CAP arm versus CAP

arm as follows: hand-foot syndrome (30% vs. 0%), anemia (15% vs. 0%), fatigue (0% vs. 11%) and abdominal pain (5% vs. 11%). Of note, incidence of Grade 1 and 2 hand-foot syndrome was similar in both the P-CAP and CAP arms (25% vs. 22%, respectively). Hand-foot syndrome is a reported adverse event with capecitabine monotherapy. Patients who remained on treatment longer in the Phase 2 study had a greater chance to develop hand-foot syndrome as illustrated by a median time to onset of Grade 3 and 4 hand-foot syndrome in the P-CAP arm of 19 weeks.

Based on the Phase 2 data, a Phase 3 randomized double-blind trial comparing perifosine + capecitabine vs. placebo + capecitabine in patients with advanced refractory colorectal cancer (X-PECT trial), under Special Protocol Assessment (SPA) from the FDA, is open and enrolling patients at multiple centers throughout the US.

Commenting on the data, Dr. Johanna Bendell, Director of GI Oncology Research at Sarah Cannon Research Institute in Nashville, TN, stated, "As the final randomized Phase 2 data confirmed the promising activity of perifosine plus capecitabine compared to placebo plus capecitabine, I believe the ongoing X-PECT trial will soon provide us an answer as to the role of perifosine in the treatment of patients with refractory colorectal cancer." Dr. Bendell is the Principal Investigator for the Phase 3 X-PECT trial.

Dr. Cathy Eng, Associate Medical Director for Colorectal Cancer at MD Anderson Cancer Center in Houston, Texas, and co-investigator in the X-PECT trial stated, "The data from the randomized Phase 2 trial continues to demonstrate the promising activity of perifosine (an oral Akt pathway inhibitor) for response, PFS, and OS in the care of previously treated, advanced colorectal cancer. We look forward to collaborating in the X-PECT trial."

Ron Bentsur, Chief Executive Officer of Keryx, commented "We are pleased by the final data, showing the promising activity of the perifosine + capecitabine combination in this very advanced colorectal cancer patient population. We believe that our Phase 3 study, in agreement with the FDA under SPA, has been designed to confirm the activity observed in this randomized Phase 2 trial."

91. The aforementioned statements in ¶ 90 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the

probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced

a statistically significant increase in overall survival rates for colorectal cancer patients.

92. On June 9, 2010, Defendant Bentsur made a presentation at the Needham Healthcare Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> With respect to Perifosine, the goal is to enroll patients aggressively into the Phase 3 programs for both colon and multiple myeloma. And we do ***expect to have data from [this study] in the second half of 2011.***
>
> . . . .
>
> I'm going to talk very briefly about the colon Phase 2 study. The data has been told to the world several times including a couple of days ago at ASCO and it was featured in a poster discussion session. I must say that the investigator who conducted the poster discussion session highlighted this study in particular is what he believes to be the most promising study and most promising compound, novel compound in the area of metastatic colon.
>
> ***And what we did in this Phase 2 was, we took patients who are second or third line metastatic colorectal patients. And we randomized them into one of two arms either Capecitabine or the other name for Capecitabine is Xeloda plus placebo versus Capecitabine plus Perifosine.*** And this was a double-blind randomized study, as I said a minute ago. And the patients with the exception of four were all third line or worse. Technically, we did have some second line patients in there, but all of the patients with the exception of four were third line or worse.
>
> Let me talk a little bit about patient demographics. It's important for people to understand that the two arms were very well balanced. Coming into the study, and that the patients were very heavily pre-treated coming in as well. ***38 patients were treated, 35 were valuable for data, the three patients that dropped out where all from the placebo group, and these are some of the other baseline characteristics in terms of age, median prior lines of therapy and the 5-FU refractory status of these patients***. And that's important to mention, because Capecitabine is a 5-FU pro-drugs that you want to make sure that there was no imbalance between the two arms, and so far as 5-FU refractory status is concerned and you can tell that the two arms were very well balanced on those parameters.
>
> Moving on to prior treatments, you can see FOLFIRI, FOLFOX, Avastin, Erbitux, these patients saw it all, a very sick patient population came into the study, and again very important to mention that the two arms were very well balanced coming into the study.
>
> I'm going to basically skip right to time to tumor progression and survival. The data has been made public several times now, so I'm not going to go into all the nooks and

crannies of the data. Suffice it to say that ***we saw statistically significant advantage in both time to tumor progression and more importantly overall survival***. You can see some of the differences that we saw between the two arms. ***With respect to the overall patient population, almost a tripling of the time to tumor progression and moving on to the 5-FU refractory subset of patients, basically a doubling of time to tumor progression. And moving onto survival, again you can see pretty much a doubling or in the case of the 5-FU refractory patient more than a doubling of overall survival. And these data were statistically significant.***

One thing that's very important to mention. ***We would be the first ones to admit that this study was not a large Phase 2 study, was 38 patients***. But one thing I'll say is ***survival doesn't lie, the second thing is if you look at the control groups both in terms of survival, what you would expect for example in the 5-FU refractory patient population,*** and I'm going to take you back one slide to the time to tumor progression, this is exactly what you would expect in terms of time to tumor progression for the control groups. If you look at all the published literature, and if you survey colorectal investigators, and I do urge you to do that, you will find that these control numbers are exactly in sync with what you would expect. And that's what ***gives us a high degree of confidence that we're actually seeing a real robust activity from this study.***

So moving onto the Phase 3 schematic basically. So we're going to be enrolling 400 patients into one of two arms, very similar to what we did in the Phase 2, capecitabine plus placebo versus capecitabine plus perifosine. And the primary endpoint is to achieve a statistically significant difference in overall survival. And 360 events of death will trigger the unblinding of the study, and ***we expect that this study will be completed with data generated in the second half of 2011***.

93. The aforementioned statements in ¶ 92 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the second half of 2011 even if perifosine

was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

94. On June 10, 2010, Defendant Bentsur made a presentation at the Jeffries Global Life Sciences Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> And with respect to perifosine, our goal is to enroll patients into the ongoing studies and ***we hope to have data from both of these studies in the second half of 2011***. . . .
> Let me first begin with Perifosine. And this is a novel oral Akt inhibitor and we've seen single agent activity across a variety of tumor types. You see some of those mentioned on the screen. Most of our effort going forward, though, at least in the near-term, is going to be in combinations with Velcade, Xeloda. Those are two efforts in multiple myeloma and metastatic colorectal respectively. And the drug does appear to be very well tolerated at the doses that we're using.
>
> Let me go back to the Phase II colon study, the one that was presented most recently in ASCO – the final data for which was presented at ASCO. I'm not going to rehash the data. I'm sure many of you have seen that basically six ways to Sunday, but a couple of key highlights from this study.
>
> ***First of all, this was a double-blind randomized study comparing two arms***. One was perifosine plus capecitabine or Xeloda versus capecitabine plus placebo. So this was obviously with an active control in it and the patients were all very sick. So technically, this was a second and third-line patient population, but with the exception of four patients, all of the patients in this study were third-line or worse.
>
> Looking at some baseline characteristics, and again, I'm sure many of you have seen it, but it's important to reinforce this point. The two arms were very well balanced coming into the study with respect to age median, prior lines of treatment, and also the 5-FU refractory status of these patients. That parameter is important because capecitabine is a 5-FU pro drug. We want to make sure that the arms are balanced with respect to the 5-FU prior treatment and status for these patients.
>
> Moving on down the line, prior treatments, overall, you can see all the treatments that these patients have seen or were exposed to prior to coming into the study. And what's important is that the two arms were very well balanced. There was certainly no distortion between the arms.

> Moving on to efficacy, I'm going to skip the response rate information and go right into time to tumor progression and survival. So with respect to time to tumor progression, ***for the overall patient population on the left, we saw more than a doubling of the median time to tumor progression in favor of the perifosine arm. With respect to the 5-FU refractory sub-group, which was about two-thirds of the patient population, we saw close to a doubling of the time to tumor progression.***
>
> ***And moving on to the Holy Grail, which is survival, that's where we see a pretty dramatic difference between the two arms. Here, it's at about 18 months versus 11 for the overall patient population. And if you look at the 5-FU refractory group and that is the group that we're going to be studying in the Phase III, you can see that we more than doubled median survival.***
>
> ***And we'd be the first ones to admit that this was not a large Phase II study. It was basically 38 patients, 35 of which were evaluable***. But a couple of key take-home points – one is, ***survival numbers don't lie***. So once you look at the median survival numbers here, you can see it's very vivid to the eye that there is a delta. That's one.
>
> Two, if you look at the control numbers for – over here, the medium survival for the 5-FU refractory patient population control group for the overall patient population, and going back to the TTP slide, looking at these numbers over here, these numbers are very consistent with what one would expect, one, if you read the published literature and also if you survey doctors. And I do urge anyone who's interested to survey as many colorectal doctors as you can possibly reach out to [] convey this. But these numbers are very consistent with what one would expect, and that leads us to believe that there is ***real activity going on here.***

95. The aforementioned statements in ¶ 94 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the second half of 2011 even if perifosine

was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

96. On August 9, 2010, the Company filed Form 10-Q ("August 2010 10-Q") with the SEC announcing its financial results for the fiscal quarter ending June 30, 2010. It stated, in relevant part, the following:

> In June 2010, we announced final results from a randomized, multi-center, double-blind, placebo-controlled, Phase 2 study of KRX-0401 (perifosine) in combination with capecitabine (Xeloda®) versus capecitabine plus placebo in patients with second- or third-line metastatic colorectal cancer. The data was presented at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago in a poster entitled, "Final results of a randomized phase II study of perifosine in combination with capecitabine (P-CAP) versus capecitabine plus placebo (CAP) in patients with second- or third-line metastatic colorectal cancer (mCRC)."
>
> ***In this randomized, double-blind, placebo-controlled study conducted at 11 centers across the United States, heavily pre-treated patients with second- or third-line metastatic colorectal cancer were randomized to receive capecitabine (a chemotherapy used in advanced metastatic colorectal cancer which is marketed by Roche as Xeloda®) at 825 mg/m2 BID (total daily dose of 1650 mg/m2) on days 1 – 14 every 21 days plus either perifosine or placebo at 50 mg daily. The study enrolled a total of 38 patients, 34 of which were third-line or greater.*** Median age of patients was 65 (32-83); 61% of the patients were male. ***Of the 38 patients enrolled, 35 patients were evaluable for response (20 patients on the perifosine + capecitabine arm and 15 patients on the placebo + capecitabine arm)***. Three patients on the placebo + capecitabine arm were not evaluable for response (2 patients were inevaluable due to toxicity (days 14, 46) and 1 was inevaluable due to a new malignancy on day 6). All patients in the perifosine + capecitabine arm were evaluable for response.
>
> The patients in the study were heavily pre-treated, with the arms well-balanced in terms of prior treatment regimens. The prior treatment regimens for all 38 patients are shown in the table below. Notably, all of the patients (with the exception of one CAP arm patient) had been treated with FOLFIRI and/or FOLFOX, almost 80% treated with Avastin®, and half treated with an EGFR antibody:

Prior RX	P-CAP (n=20)	CAP (n=18)	All Patients (n=38)
FOLFIRI	18 (90%)	16 (89%)	34 (89%)
FOLFOX	15 (75%)	13 (72%)	28 (74%)
FOLFIRI & FOLFOX	13 (65%)	12 (67%)	25 (66%)
Avastin®	15 (75%)	15 (83%)	30 (79%)
EGFR Antibody (1)	9 (45%)	10 (56%)	19 (50%)
5-FU Refractory Status	14 (70%)	13 (72%)	27 (71%)
Third Line or >	18 (90%)	16 (89%)	34 (89%)

(1) Prior treatment with Erbitux® and/or Vectibix®

The primary endpoint of this study was to measure Time to Progression (TTP). Overall Response Rate (ORR), defined as Complete Response (CR) + Partial Response (PR) by RECIST, and Overall Survival (OS) were measured as secondary endpoints.

The P-CAP arm demonstrated a statistically significant advantage for TTP and OS, as well as for the percentage of patients achieving Stable Disease (SD) or better lasting 12 or more weeks, as compared to the CAP arm. The P-CAP arm demonstrated a greater than 60% improvement in OS, a more than doubling of median TTP, and almost a doubling of the percentage of patients achieving SD or better. In addition, the ORR was 20% (including one CR, and durable responses) in the P-CAP arm versus 7% in the CAP arm. The final efficacy results are as follows:

ALL EVALUABLE PATIENTS (n=35):

Group	n	CR n (%)	PR n (%)	Duration of Response	> SD (min 12 wks) n (%) p=0.036	PD< 12 wks n (%)	Median TTP Wks p=0.0012	Median OS* Months p=0.0161
P-CAP	20	1 (5%)	3 (15%)	CR: 36 m PR: 21, 19, 11 m	11 (55%)	5 (25%)	28 [95% CI (12-48)]	17.7 [95% CI (8.5-24.6)]
CAP	15	0	1 (7%)	PR: 7 m	5 (33%)	9 (60%)	11 [95% CI (9-15.9)]	10.9 [95% CI (5-16.9)]

*Survival is calculated from date of randomization until the date of death from any cause, whether or not additional therapies were received after removal from treatment.

Of notable interest were the patients who were previously refractory to a 5-FU based regimen. The P-CAP arm again demonstrated a statistically significant increase in both TTP and OS compared to the CAP arm. The final data is illustrated below:

5-FU REFRACTORY PATIENTS (n=25):

Group	n (%)	PR n (%)	Duration of Response	> SD (min 12 wks) n (%) p=0.066	PD <12 wks n (%)	Median TTP Weeks p=0.0004	Median OS Months P=0.0112
P-CAP	14 (70%)	1 (7%)	19 m	8 (57%)	5 (36%)	18 [95% CI (12-36)]	15.1 [95% CI (7.3-22.3)]
CAP	11 (73%)	0	-	3 (27%)	8 (73%)	10 [95% CI (6.6-11)]	6.6 [95% CI (4.7-11.7)]

97. The aforementioned statements in ¶ 96 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

98. The August 2010 10-Q was also certified by Defendant Bentsur, who respectively attested to the accuracy thereof in the same form and content, except for the date of the report, set forth in ¶ 59 preceding with respect to the August 2009 10-Q.

99. Additionally, Defendant Bentsur certified under Section 906 of the Sarbanes-Oxley Act of 2002 that the "information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

100. On an August 9, 2010 conference call discussing the results for Q2 2010, Defendant Bentsur stated, in relevant part, the following:

> We presented our final Phase II data in colorectal cancer at the ASCO conference about two months ago. ***The final results confirmed the statistically significant improvement***

> ***in both time to tumor progression and overall survival in the Perifosine plus Capecitabine arm versus the placebo plus Capecitabine arm in all evaluable patients as well as in the five FU refractory group. Of particular interest, and what gives us great confidence, is the magnitude of the improvements that we saw in favor of the Perifosine arm***, and also that the control group in the study, that is the Capecitabine plus placebo arm, behaved as expected for these patients based on all available published literature and based on the surveys that we conducted with colorectal cancer experts.
>
> . . . .
>
> Approximately 40 to 50 U.S sites will participate in the study, target enrollment for the study is 430 patients. This is an event-driven study, whereby 360 events of death will trigger the unblinding of the study. Given the large patient population in the refractory metastatic colorectal setting and the limited availability of therapies for these patients, enrollment into the Phase III study is strong, and ***we believe we're well on track to complete the study in the second half of 2011***.

101. The aforementioned statements in ¶ 100 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had

been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the second half of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

102. On September 13, 2010, Defendant Bentsur made a presentation at the Rodman & Rensaw 12th Annual Healthcare Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> Let me go right to the Phase II data set that is serving as the basis for the Phase III in metastatic colorectal that is well underway. This Phase II was a randomized double-blind, placebo-controlled study, looking at second or third line metastatic colorectal patients. In fact, with the exception of four patients, all of the patients were third lined or even worse than that. ***And the patients that came into the study were randomized into one of two arms, either capecitabine, which is Xeloda chemotherapy that's used in that setting plus placebo, versus capecitabine plus perifosine***.
>
> These are the prior treatments that these patients were exposed to before coming into the study. And you can see that this is broken down by arm. And a key take-home point from the slide is that the two arms were very well-balanced coming into the study. You can see that approximately the same proportion of patients underwent FOLFIRI, FOLFOX, Avastin, EGFR inhibitors, whether it's Erbitux or panitumumab Vectibix. So, again, there were no distortions between the two arms coming into the study.
>
> I'll go right to the key efficacy parameters. Obviously, there are others, but for the benefit of time, we're going to focus on time-to-tumor progression and overall survival the data that was generated from the study. ***And what you can see here on the left side is the – all the evaluable patients from the study, there were 35 of them***. And you can see ***pretty dramatic differences in median time-to-tumor progression in favor of the perifosine capecitabine arm, versus capecitabine plus placebo.***
>
> ***Moving on to the right side over here, this is a very important subgroup to look at, it's the 5-FU refractory patients from the study. There are about two-thirds of the patients that participated in the study. And the reason the 5-FU refractory patient population is important is because capecitabine is a 5-FU pro-drug. So, patients who have failed 5-FU, you certainly would not expect them to have a dramatic response to capecitabine. And if in fact what you see here is that again a pretty dramatic difference in favor of the perifosine capecitabine arm, versus capecitabine alone, almost a doubling of the time-to-tumor progression.***
>
> And the next slide is where it gets very interesting, and this is really the focal point and the basis for the Phase III that is now ongoing, and that's overall survival. ***Looking at the left side, you can see again about 18 months versus 11 for the all evaluable patient pool and looking at the right side, the 5-FU refractory patients, again, two-thirds of the patients that participated in the Phase II, a pretty dramatic difference in median overall survival***. And that's in fact, the basis for the Phase III, which began a few months ago and this is the schematic for this Phase III, as agreed upon with the FDA under the special protocol assessment.

103. The aforementioned statements in ¶ 102 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that

perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

104. The following day, on September 14, 2010, Defendant Bentsur made a presentation at the Robert W. Baird & Co., Inc. Health Care Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> Let me talk about the Phase II data set that was generated in metastatic colorectal. This data set is serving as the basis for the ongoing Phase III. In this particular Phase II was a double-blind randomized Phase II whereby we took patients and we randomized them into one of two arms, either capecitabine which is Xeloda by its trade name, plus perifosine versus capecitabine plus placebo and the patients were metastatic colorectal patients second or third line in fact with the exception of four patients, all the patients in the study were third line or even worse than third line.
>
> Looking at some of the prior treatments that these patients have encountered before coming into the study and this is broken down by arm to give you a flavor as to the fact that the two arms were very well balanced on pretty much every parameter that you can assess. So if you look at prior FOLFIRI treatment, prior FOLFOX, Avastin, EGFRs et cetera, you can see that the two arms are very well balanced.
>
> In addition to that we wanted to see the 5-FU refractory percentage within each arm and that was important because capecitabine or Xeloda is a 5-FU pro-drug. So obviously you would not expect patients to have a dramatic response to capecitabine, if they had failed 5-FU based treatment prior there too.
>
> And again, you can see that the two arms are very well balanced. So, certainly if you look at the patient population of baseline characteristics of these patients, there are certainly no distortions that you can point out in the data.

Moving on to the key efficacy parameters. The primary end point for the study was time to tumor progression, TTP for short. ***And if you look at – on the left side, all the valuable patients, there were 35 of them. You can see a pretty dramatic difference in time to tumor progression, 28 weeks versus 11 weeks in favor of the perifosine capecitabine arm versus capecitabine placebo and looking at the right side that's the 5-FU refractory sub-group, which again is about 70% of the patients in the study. Again, you can see a pretty dramatic difference of almost doubling 18 weeks versus 10.***

Moving on to the next slide, which is really ***the Holy Grail obviously in oncology and that is to achieve a statistically significant difference or an advantage in survival and we are fortunate enough to be able to do that in the Phase II.***

Looking at the left side ***for all the valuable patients, you can see median overall survival of just under 18 months for the treatment arm. That's perifosine plus capecitabine. And just under 11 months for the control group capecitabine plus placebo.***

Moving onto the right side, which is the ***5-FU refractory patient pool, again a pretty dramatic difference of about 15 months versus approximately 6.5. And all of these were statistically significant***, and as you can imagine, we're very excited about this data.

In this bracket here is actually the most important because that's what we're going to be trying to mimic in the Phase III. So, this is the schematic for the Phase III that is now ongoing. We started that in April of this year. And essentially what we're going to be doing here is, we're going to be taking patients who are 5-FU refractory and we're going to be randomizing them into one of two arms, just like we did in the Phase II.

105. The aforementioned statements in ¶ 104 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

106. The day after that, on September 15, 2010, Defendant Bentsur made a presentation at the Stifel, Nicolaus & Company Healthcare Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> Let me talk about the Phase II dataset that was generated in metastatic colorectal, which is serving as the basis for the ongoing Phase III. This is of particular interest, and I think, generates a tremendous amount of excitement because this was a randomized double-blind study looking at metastatic colorectal patients who were second or third-line patients. In fact, with the exception of four patients in the study, all of them were third-line or worse.
>
> And what we did in this study was we randomized these patients into one of two arms. Either our drug perifosine together with capecitabine, which is a chemotherapy that also goes by the trade name Xeloda, versus capecitabine plus placebo. So again, a double-blind randomized study. And what was very important to us was to make sure that the two arms perifosine/capecitabine versus capecitabine/placebo, which is the control group, would not have any baseline distortions in it. So the two arms would need to look very similar prior to going into the study.
>
> So as you can see here, broken down by arm and there is also a total column, you can see that in terms of prior treatments that these patients saw before coming into the study, the two arms were very well balanced, FOLFIRI, FOLFOX, Avastin, the EGFR inhibitors, Erbitux, Vectibix, et cetera. And also a very important parameter for us was the 5-FU refractory status of these patients to make sure that there were no distortions between the two arms.
>
> That's important because capecitabine is 5-FU pro drug. So the likelihood of a patient having a significant response to capecitabine after having been refractory to 5-FU is remote. And you certainly don't want to see any distortions between the arms there. So I think the take-home point from this slide is that the two arms were very well balanced coming into the study.
>
> ***This is the survival data that was generated. I can tell you that across all the key efficacy parameters, we saw pretty dramatic differences between the two arms. The primary endpoint of the study was in fact time to tumor progression where we saw statistically significant differences between the two arms. We also saw a very significant advantage for the perifosine/capecitabine arm in terms of response rates and stable disease et cetera. But the Holy Grail obviously is to try to generate a survival advantage, and we in fact were able to do it in this study.***
>
> If you look to the left, you see ***all available patients from the studies, the end there with 35, and you can see a pretty dramatic difference in the median overall survival, just under 18 months versus about 11 months, so almost a doubling of the median overall survival. And then moving on to the right side, the 5-FU refractory patient who***

arguably the harder to treat patient population and the patient population that we're studying in the ongoing Phase III, you can see the differences there; about 15 months versus about 6.5. So, more than a doubling of the median overall survival in the 5-FU refractory group.

. . . .

So let's talk about the upcoming milestones for perifosine over the next, I suppose, 9 to 18 months. So we do ***expect to complete the metastatic colorectal Phase III study in the second half of 2011*** . . .

. . . .

[Analyst]: So perifosine has obviously been kind of the focal point of the transition that you guys have made here over the last 18 months or so. Both of the Phase III trials that you're running in the oncology setting are predicated off of some fairly small patient subpopulations we saw in the Phase II trial. What can you see within those patient subgroups specifically? I believe there was 14 patients in colorectal and 20 in myeloma that made you think that we needed to move forward into a Phase III trial designed for [inaudible]?

[Defendant Bentsur]: ***On the metastatic colorectal side, we had of the 38 patients that were enrolled into the study, we had about 27 who were 5-FU refractory. You're right, 14 on the perifosine, capecitabine side and 13 on the other side.*** But again these are patients that are, their prognosis unfortunately is very dismal. And the median expected survival for these patients once they reach that stage is about five months.

And again we were seeing very ***dramatic differences in survival***. And one can argue about responses and PFS, TTP, whether that's all that meaningful. ***You can't argue with survival. And particularly when you look at a patient population that is that refractory, and in the context of the magnitude of the advantage that we were seeing***, I think we felt very compelled to move forward, so . . .

. . . .

[Analyst]: So how would you characterize the pace of enrollment into the colorectal trial at this point? And are there any scheduled interim looks into the data before this thing un-blinds at the end of this – end of next year?

[Defendant Bentsur]: The pace of enrollment I would characterize as rapid. And I don't think that should come as a big surprise. We're talking about a large indication. At any given point in time there are approximately 25-ish thousand patients that qualify that would be the addressable patient population for this particular combination. These are patients that have failed FOLFIRI, FOLFOX, Avastin and EGFRs. And there's nothing out there. Nothing out there. There are no competing trials that we're aware of with novel compounds. So it's, it shouldn't come as a big surprise that we're enrolling again

> what I would categorize as, characterize as relatively rapid enrollment. And what was the second part of the question?
>
> [Analyst]: If there's any interim looks for the data?
>
> [Defendant Bentsur]: Yes. So interim looks. There is a DSMC look scheduled to look at safety and futility after half of the events. So after the 180th event, but based on our expected enrollment if you kind of extrapolate with the graphs, once we hit the 180th event, we should be pretty much fully enrolled anyway. So I'm not sure it's going to make that big of a difference.

107. The aforementioned statements in ¶ 106 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for

the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the second half of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

108. On September 22, 2010, Defendant Bentsur made a presentation at the UBS Global Life Sciences Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> . . . . I'll go right to the Phase 2 data that was generated in metastatic colorectal, which is serving [a]s the basis for the ongoing Phase 3 in metastatic colorectal.

And, in this particular Phase 2 – by the way, by trial design this was a double-blind, randomized placebo-controlled study. The patients were randomized into one of two arms, either capecitabine, you often hear that drug called Xeloda by it's trade name plus perifosine versus capecitabine plus placebo and the patients in the study were all second or third line metastatic colorectal patients. In fact with the exception of four patients all of these patients were third line or worse.

What you see here is the prior treatment of the patients before they came into the study, broken down between the two arms: perifosine capecitabine versus capecitabine placebo. And you can see that these patients were heavily pre-treated, FOLFIRI, FOLFOX, Avastin, EGFRs, and the fact that the two arms were very well balanced. So, we know that there were no major distortions between the two arms in the study and that's very important. So let's go right into the efficacy data, the primary endpoint for this Phase 2 study was time to tumor progression. And you can see on the left side, that's for the all evaluable patient population in our study. ***There were 35 of them; 38 patients were enrolled into the study, 3 dropped out and those 3 were all from the placebo group. So, for the entire pool of evaluable patients, 35, you can see pretty dramatic differences in time to tumor progression of about 28 weeks versus 11,*** that's on the left side.

On the right side, what we did was we looked at the 5-FU refractory patient group from within the patient pool and there were about 70% of the patients were 5-FU refractory in the study. The reason that's important is because capecitabine or Xeloda is a 5-FU pro-drug. So, you would not expect patients who had failed prior 5-FU therapy, which is included in FOLFOX and FOLFIRI, to have a substantial benefit from capecitabine. And we wanted to make sure that we're seeing dramatic deltas in that sub-population as well. And, in fact, ***what you see here is 18 weeks versus 10, so almost a doubling of the time to tumor progression in the harder to treat 5-FU refractory patients.***

Moving on to the Holy Grail, which is overall survival. Again, on the left side for the overall patient population, you can see again some pretty dramatic differences of just under 18 months versus approximately 11 months. And, on the right side, in the 5-FU refractory patient population, about 15 months versus 6.5 so more than a doubling of the median overall survival in the 5-FU refractory patient population.

109. The aforementioned statements in ¶ 108 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical

significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this

fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

110. On October 22, 2010, Defendant Bentsur made a presentation at BioCentury's NewsMakers in the Biotech Industry Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> Let me go right into the Phase 2 data set that was generated in metastatic colorectal which is now serving as a basis for the ongoing Phase 3 and we think this is a rather exciting data set. This was a double-blind, randomized, placebo-controlled Phase 2 study looking at metastatic colorectal patients, second or third line or worse.
>
> In fact with the exception of four patients, all of these patients were third line or worse. And what we did in this study was we randomized these two patients into one or two arms.
>
> So the patients came in and they received either perifosine which is our drug, together with capecitabine -- which also goes by its trade name, Xeloda; it's a Roche-marketed chemotherapy -- versus the control group which was capecitabine plus placebo. This gives you a flavor as to just how equal the two arms were coming into the study in terms of prior treatment and I can show you a variety of other demographic and baseline characteristics and I think you'll walk away with the same sense, that there were no distortions between the two arms.
>
> The two arms were very evenly matched coming into the study and it was very important for us to assess that. Obviously you can only assess that after the fact in a randomized double-blind study, but it was very nice to see that in fact the two arms were very well balanced primarily insofar as prior treatment is concerned -- FOLFIRI, FOLFOX, Avastin, EGFR antibodies, that's Erbitux and/or Vectibix. And another very important for us to understand was that the 5-FU refractory status of the patients was also very equal between the two arms.
>
> 5-FU refractory status is important in this setting because capecitabine is a 5-FU prodrug. So if you take a patient who is 5-FU refractory, you simply would not expect them to have a meaningful response from capecitabine as a single agent. So again, we wanted to make sure there were no distortions in our favor coming into the study and in fact there weren't any distortions.
>
> So moving on to the actual data, so time to tumor progression was the primary endpoint in this Phase 2 study, and this is where we think we're seeing a pretty dramatic advantage actually. ***Looking at the overall evaluable patient pool, 35 patients, there were 38 patients that were enrolled into the study.***

So it wasn't a big Phase 2 study, but we believe the data is fairly compelling. 35 of them were evaluable for data.

The three patients that dropped out incidentally were all from the placebo groups and no patients dropped out from the perifosine capecitabine arm. ***But diving right into the data, so the median time to tumor progression for the perifosine capecitabine arm was 28 weeks versus 11 weeks for the capecitabine perifosine arm, so more than a doubling of the time to tumor progression.***

And looking on the right side, the 5-FU refractory patient pool, again about 70% of patients were 5-FU refractory coming in, that's 18 weeks versus 10, almost a doubling of the time to tumor progression for that group. And finally looking at the Holy Grail which is overall survival, it was just under 18 months versus about 11 months for the overall patient population.

And moving on to this bracket over here which is what interests us the most because that is the patient population that we're studying in the ongoing Phase 3, ***it was about 15 months versus about 6.5. So more than a doubling of the median overall survival in the 5-FU heavily pre-treated and very refractory patient population.***

So this is the schematic for the ongoing Phase 3 [trial]. It's very similar or almost identical to what we did in the Phase 2 [trial] but obviously it's on a bigger scale.

. . . .

In terms of upcoming milestones for perifosine, so ***we believe that the metastatic colorectal study will be completed in the second half of 2011***. We expect to complete enrollment by the June timeframe of next year. Enrollment is actually going very well into that study as one would expect in such a large indication.

111. The aforementioned statements in ¶ 110 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that

the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the second half of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

112. On November 5, 2010, the Company filed Form 10-Q ("November 2010 10-Q") with the SEC announcing its financial results for the fiscal quarter ending September 30, 2010. It stated, in relevant part, the following:

> In June 2010, we announced final results from a randomized, multi-center, double-blind, placebo-controlled, Phase 2 study of KRX-0401 (perifosine) in combination with capecitabine (Xeloda®) versus capecitabine plus placebo in patients with second- or third-line metastatic colorectal cancer. The data was presented at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago in a poster entitled, "Final results of a randomized phase II study of perifosine in combination with capecitabine (P-CAP) versus capecitabine plus placebo (CAP) in patients with second- or third-line metastatic colorectal cancer (mCRC)."
>
> ***In this randomized, double-blind, placebo-controlled study conducted at 11 centers across the United States, heavily pre-treated patients with second- or third-line metastatic colorectal cancer were randomized to receive capecitabine (a chemotherapy used in advanced metastatic colorectal cancer which is marketed by Roche as Xeloda®) at 825 mg/m2 BID (total daily dose of 1650 mg/m2) on days 1 – 14 every 21 days plus either perifosine or placebo at 50 mg daily. The study enrolled a total of 38 patients, 34 of which were third-line or greater***. Median age of patients was 65 (32-83); 61% of the patients were male. ***Of the 38 patients enrolled, 35 patients were evaluable for response (20 patients on the perifosine + capecitabine arm and 15 patients on the placebo + capecitabine arm)***. Three patients on the placebo + capecitabine arm were not evaluable for response (2 patients were inevaluable due to toxicity (days 14, 46) and 1 was inevaluable due to a new malignancy on day 6). All patients in the perifosine + capecitabine arm were evaluable for response.
>
> The patients in the study were heavily pre-treated, with the arms well-balanced in terms of prior treatment regimens. The prior treatment regimens for all 38 patients are shown in the table below. Notably, all of the patients (with the exception of one CAP arm patient) had been treated with FOLFIRI and/or FOLFOX, almost 80% treated with Avastin®, and half treated with an EGFR antibody:

Prior RX	**P-CAP (n=20)**	**CAP (n=18)**	**All Patients (n=38)**
FOLFIRI	18 (90%)	16 (89%)	34 (89%)
FOLFOX	15 (75%)	13 (72%)	28 (74%)
FOLFIRI & FOLFOX	13 (65%)	12 (67%)	25 (66%)
Avastin®	15 (75%)	15 (83%)	30 (79%)
EGFR Antibody (1)	9 (45%)	10 (56%)	19 (50%)
5-FU Refractory Status	14 (70%)	13 (72%)	27 (71%)
Third Line or >	18 (90%)	16 (89%)	34 (89%)

(1) Prior treatment with Erbitux® and/or Vectibix®

The primary endpoint of this study was to measure Time to Progression (TTP). Overall Response Rate (ORR), defined as Complete Response (CR) + Partial Response (PR) by RECIST, and Overall Survival (OS) were measured as secondary endpoints.

The P-CAP arm demonstrated a statistically significant advantage for TTP and OS, as well as for the percentage of patients achieving Stable Disease (SD) or better lasting 12 or more weeks, as compared to the CAP arm. The P-CAP arm demonstrated a greater than 60% improvement in OS, a more than doubling of median TTP, and almost a doubling of the percentage of patients achieving SD or better. In addition, the ORR was 20% (including one CR, and durable responses) in the P-CAP arm versus 7% in the CAP arm.

Group	***n***	***CR n (%)***	***PR n (%)***	***Duration of Response***	***> SD (min 12 wks) n (%) p=0.036***	***PD< 12 wks n (%)***	***Median TTP Wks p=0.0012***	***Median OS* p=0.0161***
P-CAP	20	1 (5%)	3 (15%)	CR: 36m PR: 21, 19, 11 m	11 (55%)	5 (25%)	28 [95% CI (12-48)]	17.7 [95% CI (8.5-24.6)]
CAP	15	0	1 (7%)	PR: 7m	5 (33%)	9 (60%)	11 [95% CI (9-15.9)]	10.9 [95% CI (5-16.9)]

*Survival is calculated from date of randomization until the date of death from any cause, whether or not additional therapies were received after removal from treatment.

Of notable interest were the patients who were previously refractory to a 5-FU based regimen. The P-CAP arm again demonstrated a statistically significant increase in both TTP and OS compared to the CAP arm. The FINAL data is illustrated below:

5-FU REFRACTORY PATIENTS (n=25):

Group	***n (%)***	***PR n (%)***	***Duration of Response***	***> SD (min 12 wks) n (%) p=0.066***	***PD< 12 wks n (%)***	***Median TTP Wks P=0.0004***	***Median OS* Months P=0.0112***
P-CAP	14 (70%)	1 (7%)	19 m	8 (57%)	5 (36%)	18 [95% CI (12-36)]	15.1 [95% CI (7.3-22.3)]
CAP	11 (73%)	0	-	3 (27%)	8 (73%)	10 [95% CI (6.6-11)]	6.6 [95% CI (4.7-11.7)]

113. The aforementioned statements in ¶ 112 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little

more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

114. The November 2010 10-Q was also certified by Defendant Bentsur, who respectively attested to the accuracy thereof in the same form and content, except for the date of the report, set forth in ¶ 59 preceding with respect to the August 2009 10-Q.

115. Additionally, Defendant Bentsur certified under Section 906 of the Sarbanes-Oxley Act of 2002 that the "information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

116. Also on November 5, 2010, on a conference call discussing the results for Q3 2010, Defendant Bentsur stated, in relevant part, the following:

> Perifosine our oncology compound is currently in Phase III clinical development through refractory advanced colorectal cancer and for relapsed/refractory multiple myeloma, both of these Phase III programs being conducted pursuant to SPAs with the FDA and with Fast Track designations obtained for both indications. Our Phase III registration program for perifosine and colorectal called the X-PECT trial, which stands for Xeloda plus perifosine evaluation in colorectal cancer treatment, is targeting the enrollment of 430 patients in approximately 50 US sites. To update you on enrollment, I can say that enrollment is occurring rapidly and the strong momentum that we reported on the call for the previous quarter continues. ***We feel that we are on track to complete patient enrollment in June, 2011, with study completion expected sometime in the second half of 2011.*** As a reminder, this is an event-driven study, whereby 360 events of deaths will trigger the unblinding of the study.
>
> . . . .
>
> [Analyst]: Great. Great. And talk a little bit about perifosine and where you are in those studies? I think I missed when I got cut off there. In terms of the colorectal Phase III, how is enrollment going there? And then also for the multiple myeloma and to talk about just from a timing point of view, if you complete the enrollment for the colorectal study sometime mid next year, when could you have potential data?
>
> [Defendant Bentsur]: Right. So we are – we continue to make very good progress on enrollment and as more sites are coming on board, the monthly enrollment numbers get bigger by the month. So we are definitely making some very nice headway there and we're very much on target to completing enrollment by June of next year. And in terms of when the study could be completed, then if you start overlying all the extrapolation curves on when you think the events could occur, it's very likely that the study will be unblinded sometime in a second half of 2011. When exactly, is very hard to say. Obviously, we don't have that kind of resolution yet. But, again, if you put in the base case assumptions and you start running all these curves, you're probably looking at the second half of 2011 for colorectal. Which means that, if we file an NDA relatively quickly after that, with the Fast Track designation that we have in place, which should, allow for a six-month turnaround, this is a drug that could be on the market by the middle of 2012.

117. The aforementioned statements in ¶ 116 were false and/or materially misleading when made because Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the second half of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false

impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

118. On January 3, 2011, Keryx filed with the SEC a shelf registration statement on Form S-3 ("2011 Registration Statement") in order to issue up to $100 million of the Company's common shares and/or warrants.

119. On January 11, 2011, Defendant Bentsur made a presentation at the JP Morgan Healthcare Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> As you know, it's very rare, certainly for a Company our size in the biotech space, to have randomized Phase 2 data. We, in fact, have randomized Phase 2 data in metastatic colorectal. Not only do we have randomized Phase 2 data, but we've also shown a ***pretty remarkable survival advantage***, and you'll see what I mean in just a couple of slides.
>
> . . . .
>
> ***There were 38 patients who were enrolled into the study***. The two arms were very well balanced, and I'm going to take you right to the survival data. This is for all evaluable patients. ***There were 35 evaluable patients in the study, of the 38 that were randomized***. The three patients that dropped out, by the way, were all from the placebo group, so no patients dropped out from the perifosine/capecitabine arm.
>
> ***You can see a pretty dramatic survival advantage here, about 17.5 months versus just under 11, and the P value indicates a highly statistically significant score.***
>
> Moving on to the next slide, which is the 5-FU refractory patient population, ***a little over 70% of the patients in the study were 5-FU refractory. Again, a pretty dramatic difference, more than a doubling of the median overall survival in this very hard-to-treat patient population, and a highly statistically significant score, again indicating a very robust activity of the drug in combination with capecitabine.***
>
> Let me talk a little bit about the Phase 3 schematic. This is the Phase 3 under the special protocol assessment, which is well underway. I'll give an enrollment update in a moment. And essentially, we are trying to mimic the Phase 2 study, so we're going to be enrolling 430 patients into this program. These will all be 5-FU refractory patients, and we're going to randomize them just like we did in the Phase 2, capecitabine/placebo versus capecitabine/perifosine.

> The primary endpoint is to achieve a statistically significant difference in median overall survival, and 360 events of death will trigger the conclusion of the study.
>
> In terms of the expected timelines, so the study is enrolling very rapidly, and we believe that [] is also an indicator of the need for, basically, drugs in this setting, and just the sheer number of patients that are out there. We are currently enrolling at a rate of over 40 patients per month, basically at a rate of 40 to 50 patients per month. This is a U.S.-only study with over 50 U.S. sites participating.
>
> We're going to be at the halfway point, we expect, by the end of this month, and we expect full enrollment by the end of June. So, again, enrollment is moving along very rapidly and very -- we're very happy with the pace of enrollment.
>
> ***Given the fact that the 360th event will trigger the completion of the study, we expect that that will happen in the fourth quarter of 2011***, and taking into account the fact that we have fast-track designation for perifosine in multiple myeloma, we are looking at a potential drug approval in metastatic colorectal in the year 2012 for this compound.

120. The aforementioned statements in ¶ 119 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results

was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the fourth quarter of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

121. On January 28, 2011, Keryx filed a prospectus with the SEC in order to issue up to $100 million of the Company's common stock and/or warrants ("January 2011 Prospectus") pursuant to the 2011 Registration Statement. The January 2011 Prospectus also incorporated by reference the 2009 10-K, August 2010 10-Q and November 2010 10-Q, which included the false and misleading statements identified in ¶¶ 77-78, ¶¶ 96-97 and ¶¶ 112-113 respectively.

122. On March 9, 2011, the Company filed its annual report on Form 10-K ("2010 10-K") with the SEC and made the following representations with regards to perifosine:

Colorectal Cancer Clinical Data

> In June 2010, we announced updated results from a randomized, multi-center, double-blind, placebo-controlled, Phase 2 study of KRX-0401 (perifosine) in combination with capecitabine (Xeloda®) versus capecitabine plus placebo in patients with second- or third-line metastatic colorectal cancer. The data was presented at the 46th Annual Meeting of the American Society of Clinical Oncology, or ASCO, in Chicago.
>
> ***In this randomized, double-blind, placebo-controlled study conducted at 11 centers across the U.S., heavily pre-treated patients with second-, third-line or greater metastatic colorectal cancer were randomized to receive capecitabine (a chemotherapy used in advanced metastatic colorectal cancer which is marketed by Roche as Xeloda®) at 825 mg/m2, twice daily (total daily dose of 1650 mg/m2) on days 1 – 14 every 21 days plus either perifosine or placebo at 50 mg daily. The study enrolled a total of 38 patients, 34 of whom were third-line or greater***. Median age of patients was 65 (32-83); 61% of the patients were male. O***f the 38 patients enrolled, 35 patients were evaluable for response (20 patients on the perifosine + capecitabine arm and 15 patients on the placebo + capecitabine arm)***. Three patients on the placebo + capecitabine arm were not evaluable for response (2 patients were inevaluable due to toxicity (days 14, 46) and 1 was inevaluable due to a new malignancy on day 6). All patients in the perifosine + capecitabine arm were evaluable for response.
>
> The patients in the study were heavily pre-treated, with the arms well-balanced in terms of prior treatment regimens. The prior treatment regimens for all 38 patients are shown in the table below. Notably, all of the patients (with the exception of one CAP arm patient) had been treated with FOLFIRI and/or FOLFOX, almost 80% treated with Avastin®, and approximately half treated with an EGFR antibody.

Prior RX	**P-CAP (n=20)**	**CAP (n=18)**	**All Patients (n=38)**
FOLFIRI	18 (90%)	16 (89%)	34 (89%)
FOLFOX	15 (75%)	13 (72%)	28 (74%)
FOLFIRI & FOLFOX	13 (65%)	12 (67%)	25 (66%)
Avastin®	15 (75%)	15 (83%)	30 (79%)
EGFR Antibody (1)	9 (45%)	10 (56%)	19 (50%)
5-FU Refractory Status	14 (70%)	13 (72%)	27 (71%)
Third Line or >	18 (90%)	16 (89%)	34 (89%)

(1) Prior treatment with Erbitux® and/or Vectibix®

The primary endpoint of this study was to measure Time to Progression, referred to as TTP. Overall Response Rate, or ORR, defined as Complete Response, or CR, + Partial Response, or PR, by Response Evaluation Criteria In Solid Tumors, or RECIST, and Overall Survival, or OS, were measured as secondary endpoints.

The P-CAP arm demonstrated a statistically significant advantage for TTP and OS, as well as for the percentage of patients achieving Stable Disease, or SD, or better lasting 12 or more weeks, as compared to the CAP arm. The P-CAP arm demonstrated a greater than 60% improvement in OS, a more than doubling of median TTP, and almost a doubling of the percentage of patients achieving SD or better. In addition, the ORR was 20% (including one CR, and durable responses) in the P-CAP arm versus 7% in the CAP arm. The efficacy results are as follows:

ALL EVALUABLE PATIENTS (n=35):

Group	***n***	***CR n (%)***	***PR n (%)***	***Duration of Response***	***> SD (min 12 wks) n (%) p=0.036***	***PD< 12 wks n (%)***	***Median TTP Wks p=0.0012***	***Median OS* p=0.0161***
P-CAP	20	1 (5%)	3 (15%)	CR: 36m PR: 21, 19, 11 m	11 (55%)	5 (25%)	28 [95% CI (12-48)]	17.7 [95% CI (8.5-24.6)]
CAP	15	0	1 (7%)	PR: 7m	5 (33%)	9 (60%)	11 [95% CI (9-15.9)]	10.9 [95% CI (5-16.9)]

*Survival is calculated from date of randomization until the date of death from any cause, whether or not additional therapies were received after removal from treatment.

Of notable interest were the patients who were previously refractory to a 5-FU based regimen. The P-CAP arm again demonstrated a statistically significant increase in both TTP and OS compared to the CAP arm. The data are illustrated below:

5-FU REFRACTORY PATIENTS (n=25):

Group	***N (%)***	***PR n (%)***	***Duration of Response***	***> SD (min 12 wks) n (%) p=0.066***	***PD< 12 wks n (%)***	***Median TTP Wks P=0.0004***	***Median OS* Months P=0.0112***
P-CAP	14 (70%)	1 (7%)	19 m	8 (57%)	5 (36%)	18 [95% CI (12-36)]	15.1 [95% CI (7.3-22.3)]
CAP	11 (73%)	0	-	3 (27%)	8 (73%)	10 [95% CI (6.6-11)]	6.6 [95% CI (4.7-11.7)]

*Survival is calculated from date of randomization until the date of death from any cause, whether or not additional therapies were received after removal from treatment.

All 38 patients were evaluable for safety. The P-CAP combination was well-tolerated with Grade 3 and 4 adverse events of > 10% incidence for the P-CAP arm versus CAP arm as follows: hand-foot syndrome (30% vs. 0%), anemia (15% vs. 0%), fatigue (0% vs. 11%) and abdominal pain (5% vs. 11%). Of note, incidence of Grade 1 and 2 hand-foot syndrome was similar in both the P-CAP and CAP arms (25% vs. 22%, respectively). Hand-foot syndrome is a reported adverse event with capecitabine monotherapy. We believe that patients who remained on treatment longer in the Phase 2 study had a greater chance to develop hand-foot syndrome as illustrated by a median time to onset of Grade 3 and 4 hand-foot syndrome in the P-CAP arm of 19 weeks.

123. The aforementioned statements in ¶ 122 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

124. The 2010 10-K was also certified by Defendant Bentsur, who respectively attested to the accuracy thereof in the same form and content, except for the date of the report, set forth in ¶ 79 preceding with respect to the 2009 10-K.

125. Additionally, Defendant Bentsur certified under Section 906 of the Sarbanes-Oxley Act of 2002 that the "information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

126. Also on March 9, 2011, on a conference call discussing the results for Q4 2010, Defendant Bentsur stated, in relevant part, the following:

> I'll start off with an update on perifosine. Our novel oral AKT inhibitor, which is currently in Phase III clinical development, for refractory advanced colorectal cancer and for relapsed/refractory multiple myeloma. Both of these Phase 3 programs being conducted under SPAs and with Fast Track designations obtained for both indications. Our Phase 3 Registration Program under the SPA for perifosine and colorectal cancer it's called the X-PECT Trial. That stands for Xeloda plus perifosine evaluation in colorectal cancer treatment.
>
> This trial, which is being conducted in over 60 U.S. sites, is a randomized double-blind placebo controlled study comparing the efficacy and safety of perifosine plus capecitabine[]. Capecitabine is a chemotherapy that's marketed by Roche which also goes by the trade name Xeloda.
>
> So, the perifosine-capecitabine arm versus capecitabine-placebo in approximately 430 patients with refractory metastatic colorectal cancer. Specifically, these are patients that have failed all approved drugs and regimens FOLFIRI, FOLFOX, Avastin. And if there are KRAS wild-type then they will have to have failed in EGFR []antibody and that would be Erbitux and/or Vectibix.
>
> So essentially, this is a third line or greater patient population that we're looking at. The primary endpoint for the study is overall survival with secondary endpoints including overall response rate, progression-free survival, and safety.
>
> Keep in mind that this study follows ***our very successful Phase II randomized double-blind placebo-controlled study, where we show a more than doubling of overall survival in substantially the same patient population.*** To update you on enrollment into the Phase III study, I can say that enrollment is occurring rapidly and with very strong momentum, which continues.

> We are currently enrolling at a rate of approximately 40 to 50 patients per month, and as we are now well north of the halfway point, we believe that we are on track to complete the target patient enrollment for 430 patients by the end of June of this year. To remind everyone, this study is an event driven study, whereby 360 events of death will trigger the unblinding of the study. And given where we are in the enrollment phase, ***we anticipate study completion to occur in the fourth quarter of this year***, taking [] into account that we have fast track designation for this compound, we're looking at a potential drug approval for perifosine in metastatic colorectal in the year 2012.

127. The aforementioned statements in ¶ 126 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim

analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

d. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the fourth quarter of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

128. On March 14, 2011, Defendant Bentsur made a presentation at the Roth Capital Partners OC Growth Stock Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> ***In the Phase 2 study that was conducted was a randomized double-blind, placebo-controlled study across 14 clinical sites in the U.S. and essentially what we did here was patients came in and they were randomized in the one of two arms, perifosine capecitabine versus capecitabine placebo***. And this was a very heavily pretreated patient population. In fact with the exception of four patients all of these patients in a study were third line or worse.
>
> And this kind of breaks it down for you in terms of the prior treatments that these patients saw before coming into the study. ***It's actually broken down by arm, so there were 38 patients enrolled into the study and you can see the perifosine capecitabine arm and then the capecitabine placebo arm*** and then the total column on the far right and this picture really draws -- amplifies the fact that these patients were very heavily pretreated, basically having experienced everything that's available today.
>
> So FOLFIRI, FOLFOX, Avastin and about 50% of patients saw an EGFR antibody and the last row is actually very important, the 5-FU Refractory status of the patients. That's important because capecitabine, the drug that we're combining with, that we combined with in this Phase 2 and the drug that we're combining within the Phase 3 is a 5-FU pro drug.

And given the fact that 5-FU is an integral part of both FOLFIRI and FOLFOX, you certainly wouldn't expect to see any meaningful activity from capecitabine as a single agent in patients, who have gone through FOLFIRI and/or FOLFOX.

And again, the key [] take home points from the slides are that the patients were very heavily pretreated and that the two arms were very well balanced. You can see that they're in fact almost identical, there are no distortions between the arms and this is something you can plan for in the randomized study. This is something you see after effect and it was very encouraging to in fact see this.

Let me take you right to the survival data that was generated. ***We did see some very robust activity in terms of response rates, time to tumor progression et cetera. But the holy grail obviously in this type of a setting is to achieve a difference in survival and I think we saw that in a very robust fashion.***

You can see this slide here reflects all our valuable patients and the ***median overall survival achieved in the perifosine capecitabine arm was about 17.5% versus about 11% for the capecitabine placebo arm. So a pretty dramatic difference with the all valuable patient pool and a highly statically [sic] significant score as well.***

Moving on to the 5-FU refractory patients, again a little over 70% of the patients in this study were 5-FU refractory coming into the study and you can see more than a doubling of the median overall survival that 15 months versus approximately 6.5 in favor of the perifosine capecitabine arm versus capecitabine placebo also a highly statistically significant score so all very encouraging.

This takes us to the Phase 3 schematic. The Phase 3 is now very much ongoing. We started in April of last year and it is under Special Protocol Assessment and essentially what we're going to be doing here is taking 5-FU refractory patients.

They're going to be randomized one-to-one to receive capecitabine placebo versus capecitabine perifosine just like we did in the Phase 2 study, 430 patients is the target enrollment and the primary end point is to achieve a statistically significant difference in median overall survival and 360 events of death will trigger the unblinding of the study.

Just to shed a little bit of color on enrollment and on some expected timelines for this program; as the Phase 3 patient enrollment is moving along very rapidly, we now have about 62 U.S. sites participating in the study and I think we're going to stop but there has been quite significant demand on behalf of sites that wanted to participate in the study.

So obviously that's encouraging and right now we're enrolling at a pace of about 40 to 50 patients per month and given this pace, we expect to complete patient enrollment about 430 patients by the end of June of this year, which means that based on our calculations, ***we expect to hit the 360th event, which triggers the completion of the study sometime in the fourth quarter of this year.***

129. The aforementioned statements in ¶ 128 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that

perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the fourth quarter of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

130. On a May 2, 2011 conference call discussing the results for Q1 2011, Defendant Bentsur stated, in relevant part, the following:

> I'll start off with an update on perifosine, our novel oral Akt inhibitor which is currently in Phase 3 clinical development for refractory advanced colorectal cancer and for relapsed refractory multiple myeloma both of these Phase 3 programs being conducted under special protocol assessments with the FDA and with Fast Track designations obtained for both indications.
>
> Earlier this month, two posters on perifosine were presented at the 102nd annual meeting of the American Association for Cancer Research held in Orlando, Florida. The nature of the data was pre-clinical but in each study presented perifosine was observed to be enhancing the antitumor effects of the combined agent. Of particular interest was the poster with the combination of perifosine and 5-FU in gastric cell lines in which perifosine enhance the antitumor activity of 5-FU including in 5-FU resistant cell lines demonstrating a synergistic effect. As a reminder, 5-FU is the active metabolite of the pro-drug Xeloda or capecitabine. ***All of this information is encouraging as the results***

which are in line with other studies demonstrating the synergistic effects of perifosine with certain cytotoxic drugs including bortezomib and 5-FU provides further validation for our Phase 3 studies particularly our ongoing Phase 3 colorectal cancer study, the X-PECT trial in which we're looking at the perifosine Xeloda combinations.

The X-PECT trial which stands for Xeloda plus Perifosine Evaluation in Colorectal Cancer Treatment is being conducted in over 60 U.S. sites and this is a randomized double-blind, placebo-controlled study comparing the efficacy and safety of perifosine plus capecitabine or Xeloda versus capecitabine plus placebo in approximately 430 patients with third line or greater refractory metastatic colorectal cancer. The primary endpoint is overall survival with secondary endpoints including overall response rate, progression free survival and safety. This study is very similar to ***our highly-successful Phase II randomized double-blind placebo-controlled study, where we showed a more than doubling of overall survival in a very similar 5-FU-refractory patient population***.

To update you on enrollment into the Phase 3 study, I can say that enrollment is occurring rapidly and the strong momentum continues. We currently have well over 300 patients enrolled into the study and we maintain our earlier guidance that were on track to complete target patient enrollment by the end June of this year. This is an event-driven study whereby 360 events of death will trigger the unblinding of the study. ***We expect that the 360th event will occur in the fourth quarter of this year and this will trigger the unblinding and thus the completion of the study.***

. . . .

[Analyst]: Great. And then just one other question on perifosine with respect to colorectal cancer program third line, could you give us a little bit more detail in terms of the timing and where you are and then expected timing for, potential timing for filing for approval on that program?

[Defendant Bentsur]: So as I mentioned during the call, we expect to complete enrollment by the end of June, 430 patients approximately. In terms of the events based on our power calculations and the way we are internally extrapolating when those events should occur, ***we expect that the 360th event will occur in the fourth quarter of this year*** and as you know, the 360th event is what triggers the unblinding of the study. So therefore***, we believe that the study could be completed in the fourth quarter of this year.*** Again this is based on our internal extrapolation curves.

131. The aforementioned statements in ¶ 130 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the

initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients

enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the fourth quarter of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

132. On May 4, 2011, the Company filed with the SEC a Prospectus Supplement to the January 2011 Prospectus ("May 2011 Prospectus Supplement") issuing approximately 7 million shares of its common stock priced at $4.70 per share for gross proceeds of approximately $33 million. Total net proceeds from this offering were approximately $30.8 million. The May 2011 Prospectus Supplement also incorporated by reference the 2010 10-K, which includes the false and misleading statements identified in ¶¶ 122-123.

133. As late as June 30, 2011, Keryx published on its website (www.keryx.com) that "***[Perifosine] has demonstrated both safety and clinical efficacy in several tumor types, both as a single agent and in combination with novel therapies. [Perifosine] is currently in Phase 3 clinical development for . . . refractory advanced colorectal cancer . . .***"

134. The aforementioned statements in ¶ 133 were false and misleading because perifosine was an investigational new drug not approved by the FDA, and therefore, could not be

advertised as safe or effective. In fact, the FDA sent a warning letter to Keryx on or about June 30, 2011 stating, in relevant part, the following:

> The Keryx website makes numerous statements that promote [perifosine] as safe and/or effective for the purposes for which it is being investigated or otherwise promote the drug. For example, the *About Us* and *Product Pipeline* sections of the Keryx website include statements such as the following:
>
> - [Perifosine] has demonstrated both safety and clinical efficacy in several tumor types, both as a single agent and in combination with novel therapies.
>
> - Its safety profile is distinctly different from that of most cytotoxic agents. [Perifosine] does not appear to cause flu-like symptoms, thrombocytopenia (decrease in platelets that may result in bleeding) or alopecia (hair loss); all of these toxicities occur frequently with many of the currently available treatments for cancer. The main side effects of [perifosine] are nausea, vomiting, diarrhea and fatigue, but these are generally well-managed particularly at lower daily doses (50 mg or 100 mg) that have induced tumor regression.
>
> - These trials demonstrated that [perifosine] can be safely given to humans with a manageable toxicity profile.
>
> - [Perifosine] has generally been well tolerated when used as a low daily dose (50 mg or 100 mg) in combination with these approved agents.
>
> These claims suggest that KRX-0401 is safe and/or effective for the treatment of various kinds of tumors, both as a single agent and in combination with other therapies, when it has not been approved for these uses. Additionally, the totality of the above-referenced claims makes the conclusions that the drug is well-tolerated, can be safely given to humans with a manageable toxicity profile, and has a safety profile that is "distinctly different from that of most cytotoxic agents."
>
> Since KRX-0401 is an investigational new drug, the product's indication(s), warnings, precautions, adverse reactions, and dosage and administration, have not been established and are unknown at this time. Keryx's promotion of KRX-0401 as safe and effective for purposes for which it is under investigation, by making representations such as those noted above, is in violation of 21 CFR 312.7(a). We note that the website includes the disclaimer that states, "This investigational drug product has not been approved by the US Food and Drug Administration for safety and effectiveness. This investigational drug product is still undergoing clinical study to verify its safety and effectiveness." ***However, this disclaimer is not sufficient to mitigate the overwhelming misleading impression conveyed by claims on Keryx's website, such as those noted above, that KRX-0401 is safe and effective.***

> **Conclusion and Requested Action**
>
> For the reasons discussed above, the website violates the Act and FDA implementing regulations. 21 CFR 312.7(a). These statements are concerning from a public health perspective because they make promotional claims about the safety and efficacy of an investigational new drug that has not been approved by the FDA.
>
> DDMAC requests that Keryx immediately cease the dissemination of violative promotional materials for KRX-0401 such as those described above. Please submit a written response to this letter on or before July 15, 2011, stating whether you intend to comply with this request and explaining your plan for discontinuing use of such violative materials. . . .
>
> The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your materials for KRX-0401 comply with each applicable requirement of the Act and FDA implementing regulations.

135. On July 27, 2011, the Company issued a press release announcing the completion of patient enrollment for the Phase 3 trial with perifosine in refractory advanced colorectal cancer.

136. On August 8, 2011, the Company issued a press release announcing its second quarter 2011 financial results. In the press release, Defendant Bentsur stated, in relevant part:

> During the quarter, we made significant progress in our Phase 3 programs. With the announcement last week of completion of enrollment into our Perifosine Phase 3 program in advanced refractory colorectal cancer, ***we are only several months away from the completion of this important study***.

137. The aforementioned statements in ¶ 136 were false and/or materially misleading when made because Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) within "only several months" even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

138. That same day, August 8, 2011, on a conference call discussing results for Q2 2011, Defendant Bentsur stated, in relevant part, the following:

> I'll provide a more detailed update on perifosine, our novel, oral Akt inhibitor, which is currently in Phase 3 clinical development for refractory advanced colorectal cancer and for relapsed refractory multiple myeloma. In addition to having SPAs for each of these programs, the compound has also received fast-track designation for both indications.
>
> As I briefly mentioned at the outset, very recently we announced the completion of enrollment into our ongoing Phase 3 X-PECT study of perifosine in the treatment of refractory patients with advanced colorectal cancer. We exceeded the original target enrollment of 430 patients as we now have over 465 patients enrolled in the study, slightly over-enrolling, which we view as a positive.
>
> We're sincerely grateful to our investigators and the research teams for their dedication and commitment in recruiting patients for this important study. I would also like to thank the top-notch clinical group that we have at Keryx. Keryx is a small company with limited resources and I commend our clinical group for its work.
>
> The X-PECT trial, which stands for Xeloda plus Perifosine Evaluation in Colorectal cancer Treatment, is being conducted in U.S. sites only. This is a randomized double-blind placebo-controlled study comparing the efficacy and safety of Perifosine plus capecitabine or Xeloda versus capecitabine plus placebo in now over 465 patients with third line or greater refractory metastatic colorectal cancer. The primary endpoint is overall survival with secondary endpoints, including overall response rate, progression-free survival or PFS and safety. This study is very similar to our ***highly successful Phase 2 randomized, double-blind, placebo-controlled study, where we showed a more than a doubling of the median overall survival in a very similar 5-FU refractory patient population. This is an event-driven study whereby 360 events of death will trigger the unblinding and completion of the study.***
>
> ***We expect that the 360th event will occur in the fourth quarter of 2011***. . . .
>
> . . . .
>
> [Analyst]: And then with regard to your thoughts on timing of when you think that that will – that trial will be completed, is that reflective of any current event rates or you're just using your historical kind of thoughts in terms of how long that trial will take?
>
> . . .
>
> [Defendant Bentsur]: ***Regarding timing, so, this is essentially based on historical kind of extrapolation curves that obviously we have internally. And again, we've always said that we believe that the [360th] event should occur in the fourth quarter, and we still are sticking to that. Obviously if things will change, we will be alerted of that. And***

obviously we will probably disclose the time change in due course. But right now, we still believe that the [360th] event should occur in sometime in the fourth quarter. When exactly in the fourth quarter? It's very hard to say.

. . . .

[Analyst]: Good. Thanks for taking my question. I just wanted to get a little more – I guess a little more background on what you expect later this month or early next month with the DSMC? . . . .

[Defendant Bentsur]: So, first of all the DSMC analysis, so that's going to happen at the end of August or at the beginning of September. Essentially this was always part of the protocol and part of the stat plan. So despite the fact that I think the practicality of it is fairly low at this juncture, given the fact that we're fully enrolled and we expect to have data within several months. Again I think that from a practical perspective, I just don't see that tremendous value of having the DSMC look.

However, it is in the protocol, it is in the SPA, so we're going ahead and doing it. And essentially, the end of August or early September was arbitrarily picked as a date. It's designed to capture roughly half of the events. I think we're a little bit below half of the events right now as far as I know. That's 100, a little bit less than 180 events right now, but basically they're going to take whatever data they get from the CRO this week basically. They're going to digest it and they're going to meet within about two to three weeks. And this is an analysis that's designed to assess safety and futility. And again there could be several recommendations that come out, the worst of which obviously is – we're seeing a very bad safety signal or we're seeing very significant futility here and you should stop the study.

Obviously, we're certainly hoping that that won't be the case. And really the other possibility is continue as planned. Keep in mind that the DSMC is entitled to do – they're at liberty to do whatever they want. . . .

139. The aforementioned statements in ¶ 138 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that

the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the fourth quarter of 2011 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

140. On August 31, 2011, the Company issued a press release announcing that an independent data safety monitoring board completed a pre-specified interim analysis for safety and futility in the Phase 3 X-PECT study and recommended that the study continue to completion.

141. On October 19, 2011, before the market opened, TheStreet.com published an article by Adam Feuerstein entitled "Keryx: Readers React to Perifosine Prediction." The article stated, in relevant part, the following:

> The strongest, most reliable, clinical data comes from randomized, controlled studies. No disagreement there. I've long criticized biotech companies that run crappy single-arm phase II studies and then make dubious survival-benefit claims based on comparisons to outdated "historical" data. Blech.
>
> Ratain has also been a vocal proponent of randomized studies and believes the high failure rate in cancer drug development stems, in large part, from the over-reliance on single-arm trial designs.
>
> As he says above, Ratain also believes the perifosine phase II study is flawed, despite what looks to be a randomized, controlled clinical trial design.
>
> As originally conducted, the phase II study was designed to determine perifosine's signal of activity. Initially, 381 patients diagnosed with seven different types of cancer and treated with eight separate chemotherapy regimens were to be enrolled in the study. Within each tumor type, patients were to be treated with either perifosine or a placebo.
>
> Full enrollment in the study never took place. Instead, an unplanned interim analysis was conducted which revealed evidence of clinical activity when perifosine was combined with capecitabine (sold by Roche under the brand name Xeloda) in 25 colon cancer

patients. Based on this unplanned analysis, the original study design was abandoned and instead, an additional 13 colon cancer patients were enrolled in the study to bring the total number of colon cancer patients to 38.

It's data from these 38 colon cancer patients -- which again, purports to show a survival benefit favoring the perifosine-capecitabine combination over capecitabine alone -- that Keryx relied upon to design the ongoing phase III study.

Ratain cites the following specific criticisms of the perifosine phase II study:

1) The p values are not real p values in the phase II study, as there were eight drugs being studied, multiple diseases, and an unknown number of looks at the data. [He recommends people read "Fooled by Randomness."]

2) Thus the first 25 patients (of the 38 reported) can only be considered hypothesis generating, since the observed nominal p value could be ascribed to data dredging.

3) The additional 13 patients are inadequate to assess the hypothesis of interest, particularly since we don't know the baseline characteristics of the additional 13 patients, including their refractory status to previous treatments. Therefore, the phase II results are un-interpretable.

4) In the absence of interpretable phase II data, the phase III will probably be negative, given what is known (publicly) about the drug's pharmacology.

5) Given the likelihood that deep pockets have looked at and rejected an acquisition or partnership based on nonpublic data (after signing a non-disclosure agreement), there is no reason to predict that the phase III will be positive.

Understand? If not, try this simplified interpretation: The phase II study of perifosine is too small and was changed and analyzed too often to have confidence in the published results. The clinical benefit, including survival, favoring perifosine that was observed in the phase II study stands a good chance of returning a false positive result that will not be confirmed in the larger and prospectively designed phase III study.

142. Following the publication of Feuerstein's article, Keryx's common stock dropped approximately 6% to close at $2.75 on October 19, 2011.

143. On a November 3, 2011 conference call discussing the results of Q3 2011, Defendant Bentsur stated, in relevant part, the following:

In the third quarter, we completed patient enrollment into the [Phase 3] study, with over 465 patients randomized at approximately 65 US sites. ***We currently expect to report top-line data in the first quarter of 2012.***

. . . .

[Analyst]: Can you talk a little bit about, if it's possible, sort of the slope of the curve or how the event rates are progressing? I know that at least earlier this year, we were thinking that the events would occur by the end of this year, close to the end of this year. That's been pushed out. Can you give us any sort of feedback as to how things are looking? And when might you get another update? And is it possible that the events could slow down enough that it gets pushed out again to maybe the second quarter of 2012?

[Defendant Bentsur]: So, as you've touched on – when the Data Safety Monitoring Committee conducted its analysis, they were looking at a data which had a cut-off date of August 5, I believe. And based on our extrapolations leading up to that date, we had thought that we would have a little bit north of half of the events by that time point. So, we were expecting anywhere between 180 to maybe 185 events or something like that. It ended up that the DSMC looked at approximately 163 events. ***So, it does appear, at least based on that data cut-off, that we're tracking at about 10% slower, which anecdotally, I think, is better than certainly having it the other way around.***

With respect to additional updates on events, we haven't received any. However, obviously, the CRO is going to keep us apprised as we get closer to the 360-event mark. ***And obviously, there could be some time changes, but we still project that the 360th event will occur in the first quarter and that the top line release will also come out in the first quarter***. That is the best information that we have right now.

[Analyst]: And, Ron, do they – does the CRO give you updates, like on a monthly basis? Will there be another DSMB assessment of the safety between now and the first quarter?

[Defendant Bentsur]: No, there will be no additional Data Safety Monitoring Committee looks. This was a one pre-specified look as part of the SPA. There will be no additional looks. The CRO will update us. The agreement is that the CRO will update us as we get closer.

. . . .

[Analyst]: Just a follow-up on a couple of questions, follow-up on one of Ren's questions in terms of the timing aspect. Once the data is locked, so to speak, how much – or once you hit your 360th event, how much time does it take to really scrub that data and be able to have top line results?

[Defendant Bentsur]: It typically takes anywhere from four to eight weeks. We think we're going to be hopefully on the lower end of that.

[Analyst]: Okay, great. And you said that you could – you expect that 360th event sometime the first quarter?

[Defendant Bentsur]: Yes.

144. The aforementioned statements in ¶ 143 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the first quarter of 2012 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine; and

b. When asked about the timing of the 360th patient death, Defendant Bentsur misled investors by creating that false impression that the delay was "better than" having the deaths occur ahead of schedule. As a result, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

145. On November 16, 2011, Defendant Bentsur made a presentation at the Lazard Capital Markets Health Care Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> With that, I'm going to switch gears and talk about our oncology compound, the compound called perifosine. And again, it's a novel oral Akt Inhibitor and we've seen some very interesting clinical activity with perifosine across the variety of tumor types. You can see some of the names of these tumors mentioned here on the slide RCC, sarcoma, CLL et cetera. But our efforts right now are actually in combinations with other approved agents. So, for example metastatic colorectal, we're combining with capecitabine or Xeloda, as that's the capecitabine trade name. And in multiple myeloma, we are combining with Velcade. And the drug appears to be very well tolerated at the doses that we're using.
>
> Let me talk about the metastatic colorectal program, that is the one that's going to read out first and that is truly a blockbuster potential for us. ***The Phase 2 study that we***

conducted in metastatic colorectal was a randomized double blind placebo controlled study. It was conducted across 14 sites in the U.S. and essentially what we did here was patients came in and they were randomized to receive capecitabine plus perifosine versus capecitabine plus placebo. And this was a very heavily pretreated patient population, as you see on this slide, this breaks it down by arm. ***You can see that there were 38 patients enrolled into the study. So, it wasn't a big Phase 2, but the two arms were very well balanced coming into the study, you can see the prior treatments FOLFIRI, FOLFOX, Avastin et cetera***.

There are really know [sic] distortions that you can point to in terms of comparing the two arms, the two arms prior treatments before coming into the study. Another very important point to mention is the bottom row, which is the 5-FU refractory status of these patients. Keep in mind that capecitabine is a 5-FU pro-drug. So, the likelihood of any patient seeing a meaningful benefit from capecitabine as a single agent after having failed 5-FU based regimen, which are an integral part of FOLFIRI and FOLFOX, the likelihood of that is fairly remote. As it was very important for us to understand the proportion of patients who are actually 5-FU coming into the study and to make sure that there were no distortions. And obviously, this is all information you find out after the test in the double-blind randomized placebo-controlled study.

I'll take you right to the highlight which is ***the survival data looking at the 5-FU refractory patients in the study. You can see a pretty dramatic difference in median overall survival, about 15 months with the perifosine capecitabine arm versus about six and a half months for the capecitabine placebo arm***. ***And we're interested in the 5-FU refractory patients, because that is what we are doing in the Phase 3.*** And I am going to take you right to the schematic of the ongoing Phase 3. We actually over enrolled a target randomization with 430 patients, we slightly went above that to about 465, randomized into one of two arms, just like we did in the Phase 2. Capecitabine placebo versus capecitabine perifosine, all of these patients will have to have failed FOLFIRI, FOLFOX, Avastin, and if they are KRAS wild type and EGFR that's the Erbitux and/or Vectibix. ***The primary endpoint is median overall survival and 360 events of that will trigger the unwinding of the study. And we expect that in the first quarter of 2012***. So, in terms of just a little bit more detail on the timelines, we talked about patient enrollment, the study, the U.S. only study conducted across approximately 65 centers in the U.S. We did have an independent data safety monitoring committee reviewed for safety and futility that occurred in August. The recommendation was to move forward as planned. And ***the study completion, as I alluded to is expected in the first quarter of 2012***. And keep in mind that we do have fast track designation for the compound, so, we also receive priority review. So, this drug could be on the market by the end of 2012.

146. The aforementioned statements in ¶ 145 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2

protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

d. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the first quarter of 2012 even if perifosine

was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

147. On December 8, 2011, before the market opened, Seeking Alpha published an article by Adam Gefvert entitled "Why Perifosine Phase 3 Trails Will Likely Fail." The article stated, in relevant part, the following:

> This article by The Street biotech expert Adam Feuerstein analyzes Keryx (KERX) and Aeterna Zentaris (AEZS) who jointly created the cancer drug Perifosine and suggests that its phase 3 trial, the results of which will be out in early 2012, will most likely fail. He presents his findings in conjunction with Mark J. Ratain, MD. Dr. Ratain has quite an impressive bio, as shown on Forbes here. He has authored and co-authored more than 350 articles and book chapters. He received his A.B. degree from Harvard University and his M.D. from the Yale University School of Medicine.
>
> Mr. Feuerstein presents what he calls the "Feuerstein-Ratain rule" which states that the outcome of phase 3 cancer drug studies can be predicted accurately by looking at the market value of the company running the study. It's derived from an analysis of 59 phase 3 clinical trials of cancer drugs conducted over the past 10 years. The list of drug trials wasn't put together by Feuerstein or Ratain, but by a paper published in the Journal of the National Cancer Institute.
>
> The study showed that 21 out of 21 phase 3 cancer drug trials for micro-cap companies (companies with less than $300 market cap) failed, whereas 21 of 27 phase 3 trials by the larger companies analyzed (with a greater than $1 billion market cap) were positive. The apparent reason for this disparity is because pharmaceutical stock investors are astute and can accurately predict outcomes of phase 3 trials based on how the phase 1 and 2 trials went.
>
> Keryx and Aeterna Zentaris are both micro-cap stocks.
>
> A 100% failure rate is a compelling statistic, and suggests a short of both KERX and AEZS would be a good binary bet right before the phase 3 trial results come out in early 2012.
>
> Dr. Ratain believes the phase 2 study of Perifosine is flawed and not as randomized as it should be. Initially, 381 patients diagnosed with seven different types of cancer were to be enrolled in the therapy. With each tumor type, patients were to be treated with either Perifosine or a placebo.

> However, this study never took place. Instead, it was revealed that there were good results when combining Perifosine with Capecitabine in 25 colon cancer patients. So KERX jumped on this and took the other cancer patients out of the study and added 13 new colon cancer patients to bring the total number of patients to 38. The data of these 38 colon cancer patients showed a survival benefit favoring the Perifosine-Capecitabine combination over Capecitabine alone. This qualified as a pass for phase 2, which brought on the phase 3 study.
>
> Dr. Ratain has various criticisms of the study. Mainly that singling out only the 25 colon cancer patients was data dredging, and can only be considered hypothesis generating. Adding only 13 to the group is inadequate to assess the hypothesis. Also, we don't know the baseline characteristics of the additional 13 patients, including their refractory status to previous treatments. Therefore, the phase 2 results are un-interpretable.
>
> Because of these criticisms, Ratain believes there's a good chance the larger and prospectively designed phase 3 study will fail.

148. Following the publication of Gefvert's article, Keryx's common stock dropped approximately 6% to close at $2.64 on December 8, 2011.

149. On January 12, 2012, Defendant Bentsur made a presentation at the JP Morgan Global Healthcare Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> Let me talk about the metastatic colorectal program and before I talk about the Phase III, I want to give you basically a recap of what we saw in the Phase II. ***So we conducted a double-blind randomized Phase II study looking at metastatic colorectal patients. This study was conducted across 14 clinical sites in the US and essentially patients came in and were randomized to receive either capecitabine, Xeloda, plus a placebo versus capecitabine, plus perifosine***. And this was a very heavily pretreated patient population as the next slide, this one, that is being shown now demonstrates. You can see here the patient population broken down by arm and you can see the prior treatments that these patients saw before coming into the study. And obviously, a clear conclusion from this slide is that the patients were very heavily pretreated and that the patients were -- or the two arms were very well-balanced before coming into the study.
>
> I want to draw your attention to the final, to the last row, the 5-FU refractory status of the patients and here, we basically show the percentage of patients who were 5-FU refractory coming into the study. The reason that is important is because capecitabine or Xeloda comes from the 5-FU family. So you certainly wouldn't expect to see any activity of Xeloda on its own, any meaningful activity rather, in patients that have failed 5-FU-based regimens outright.

Moving onto the most important slide, the take-home slide from the Phase II study and that ***is the survival benefit that we saw, in particular in the 5-FU refractory patient group and you can see a pretty dramatic difference in median overall survival, a little bit more than a doubling of median overall survival in this patient population***. So obviously, that intrigued us very much and we wanted to take this product forward into Phase III, which is what we are doing now.

We are nearing completion and this is the schematic or the trial design for the Phase III. Patients will have to be 5-FU refractory. They will have to have gone through FOLFOX, FOLFIRI, Avastin and if they are KRAS wild type, they will have to have failed and EGFR antibody, possibly even both and patients will come in and patients were randomized into one of two arms just like we did in the Phase II capecitabine plus placebo versus capecitabine plus perifosine. And the primary endpoint is median overall survival and 360 events will trigger the unblinding of the study. I will touch on that in a slide -- on the next slide actually.

We completed enrollment in the summertime. Approximately 465 patients were recruited. This was a US-only study across 65 clinical sites in the US. We did have an independent data safety monitoring committee review in August looking at safety and futility. Their recommendation was to move forward as planned. And as I mentioned before, ***study completion will occur upon the 360th event. That event has not occurred yet nor have we received word from the CRO that that event is imminent. Therefore, we are basically very much in the dark just like everyone else. We still believe that this is going to be a first-quarter event.***

150. The aforementioned statements in ¶ 149 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had

neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the first quarter of 2012 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the

study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

151. On February 14, 2012, Defendant Bentsur made another presentation at the BIO CEO and Investor Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> I'm going to talk about the metastatic colorectal program in a little bit more detail. First, let me just touch on the Phase 2 study that was conducted with perifosine in metastatic colorectal, which is serving as the basis for the Phase 3, which is nearing completion. ***The Phase 2 is a randomized double-blind placebo controlled study conducted across 14 clinical sites in the U.S***. ***And in this study, patients came in and they were randomized to receive either perifosine plus capecitabine or Xeloda versus capecitabine plus placebo***. And this was a very heavily pretreated patient population.
>
> You can see on this slide that it's broken down by arm, just how heavily pretreated these patients were coming into the study. And another thing that draws your – probably draws your attention is the fact that the two arms are very well balanced in terms of these prior treatments. The last row is actually the one that is very interesting to us, and that is what is the portion of the patients that were 5-FU-refractory coming into the study. The reason that is important is because capecitabine is a 5-FU pro-drug. It comes from the 5-FU family. So the likelihood of a patient who has failed outright a 5-FU based regimen, the likelihood of that patient to see any meaningful activity from capecitabine, we believe is fairly unlikely.
>
> Taking you right to the highlight of this Phase 2 study, the survival data that was generated. And you can see a ***pretty dramatic difference in favor of the perifosine capecitabine arm in terms at [sic] median overall survival versus capecitabine placebo and the result was also highly statistically significant even though the patient population was not big, 38 patients***. And obviously that elevated our interest level in this program and basically led us to conduct the Phase 3 study which again is nearing completion and this is the schematic for the Phase 3 program which is ongoing and the original target enrolment [sic] with 430 patients and the goal was to randomize the patients 1:1 to receive either capecitabine placebo or capecitabine perifosine.
>
> And the primary endpoint of the study is median overall survival and 360 events of death will trigger the unblinding. And just in terms of the patient population that is coming into the study, all of them will have to be 5-FU-refractory, all of them will have to have failed FOLFOX, FOLFIRI, Avastin and if they're KRAS wild-type one or both of the EGFRs that are on the market.

> And in terms of timelines where are we right now? So patient enrollment was completed in early August. We actually overenrolled slightly, 465 – approximately 465 patients were enrolled into the study. There was an independent data safety monitoring committee, analysis for safety and futility. That was conducted at the end of August. And as I mentioned before, study completion, the triggering of the unblinding will occur when the 360th event will happen. That has not occurred yet nor have we heard from the CRO that the 360th event is imminent. That said, ***we still expect that the 360th event will occur in the first quarter of this year.***

152. The aforementioned statements in ¶ 151 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity

issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

e. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the first quarter of 2012 even if perifosine was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

153. On February 27, 2012, Defendant Bentsur made another presentation at the Citi Global Healthcare Conference. In that presentation, Defendant Bentsur stated, in relevant part, the following:

> Let me talk about the metastatic colorectal program first. Before I talk about the Phase III, I want to talk about the Phase II that was conducted that is basically serving as the basis for the Phase III study. ***And the Phase II was a randomized, double-blind, placebo-controlled study. It was conducted across 14 clinical sites in the US. And essentially what we did here was patients came in and they were randomized to receive either perifosine, which is our drug, together with capecitabine or Xeloda versus the control group, which was capecitabine plus placebo***.

And the patients were very heavily pretreated before coming into the study and this gives you a flavor of just what these patients saw before coming into the study. And you can see it broken down by arms, perifosine capecitabine, capecitabine placebo and then the overall patient population. And you can see that all of these patients essentially experienced FOLFIRI, FOLFOX and about three-quarters of them basically went through Avastin, about 50% in EGFR antibody.

And it's the last row that is really of interest to us, the 5-FU refractory status of the patients. Essentially what proportion of the patients were 5-FU refractory coming into the study? The reason that is important is because capecitabine comes from the 5-FU family. It's essentially a 5-FU prodrug. So the likelihood of a patient who has failed a 5-FU-based regimen to see any meaningful activity from capecitabine as a single agent, we believe that that likelihood is fairly remote. You can see that approximately 70% of the patients were 5-FU refractory coming into this study and overall, when you look at this slide, you can see that the two arms were very well balanced, there are no distortions that you could point to and that the patients were very heavily pretreated.

This leads us to the most important conclusion from this particular Phase II study, which is the survival data looking at the 5-FU refractory subgroup. Again, this was not a big study; it was 38 patients, but I think the data here is very telling. You can see about 15 months of median overall survival for the treatment arm versus about 6.5 months for the control group. Obviously, a very visible delta between the two groups.

And this, obviously, was very intriguing to us and this led us to conduct the Phase III study, which is nearing completion and this is the schematic for the Phase III study. And essentially what we're doing here is essentially mimicking the Phase II study for the 5-FU refractory patients. All of the patients in our Phase III will have to have seen FOLFOX, FOLFIRI, Avastin and if they are KRAS wild-type, then an EGFR, that's Erbitux and/or Vectibix. And the target enrollment was 430 patients. We exceeded that. You'll see that on a later slide. And the primary endpoint is median overall survival and 360 events of death will trigger the unblinding of the study.

This leads us to a snapshot in time. Where are we right now in terms of the study? So in terms of patient recruitment, we enrolled approximately 465 patients; we completed enrollment in early August. 65 US sites are participating in the study, so this is a US-only study. We did have an independent data safety monitoring committee review for safety and futility. That was conducted in late August of last year. ***And in terms of the study completion, the 360th event, that event has not occurred yet. However, the CRO has communicated to us recently that they feel strongly that the 360th event will occur in March. And we just don't have any more specifics beyond that at this point.***

154. The aforementioned statements in ¶ 153 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2

protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients; and

d. Defendants knew or recklessly disregarded the fact that the Phase 3 X-PECT study would (or could) be completed later than the first quarter of 2011 even if perifosine

was ineffective in meeting the study's primary endpoint of extending overall survival of the study's patients by two months. As a result of the omission of this fact, investors were given the false impression that any delays in the reporting of top line results of the study were attributable to increased overall survival in those patients receiving perifosine.

155. On February 29, 2012, the Company issued a press release announcing fourth quarter and year-end 2011 financial results. Defendant Bentsur stated, in relevant part, the following:

> During the fourth quarter of 2011, we remained focused on our three ongoing Phase 3 studies. ***With the completion of our Perifosine Phase 3 study in metastatic colorectal cancer expected in March, we look forward to the top-line data release within several weeks thereafter.***

156. The aforementioned statement in ¶ 155 was false and/or materially misleading when made because Defendants knew or recklessly disregarded that the results of the Phase 3 X-PECT study could not have been released as set forth in ¶ 163 below because Defendants knew or recklessly disregarded that it would take significantly less than several weeks to audit the accuracy of and process the data needed to confirm the study's top line results.

157. On a March 1, 2012 conference call discussing the results of Q4 2011, Defendant Bentsur stated, in relevant part, the following:

> As we have previously stated, study completion will occur upon the approximately 360th event of death. I would like to update everyone that ***the 360th event has not occurred yet***; however, as I mentioned at an investor conference earlier this week, we have been advised that the 360th event is expected to occur this month. We don't have any more specifics on the timing of the 360th event. ***We expect that the top-line data release will take place within several weeks after study completion***.

158. The aforementioned statement in ¶ 157 was false and/or materially misleading when made because Defendants knew or recklessly disregarded that the results of the Phase 3 X-PECT study could not have been released as set forth in ¶ 163 below because Defendants knew

or recklessly disregarded that it would take significantly less than several weeks to audit the accuracy of and process the data needed to confirm the study's top line results.

159. On March 2, 2012, the Company filed its annual report on Form 10-K ("2011 10-K") with the SEC and made the following representations with regards to perifosine:

> The primary endpoint of this study was to measure Time to Progression, or TTP. ORR, defined as Complete Response, or CR, + Partial Response, or PR, by Response Evaluation Criteria in Solid Tumors, or RECIST, and Overall Survival, or OS, were measured as secondary endpoints. ***The efficacy results illustrated by ORR, TTP and OS, broken down by all evaluable patients and 5-FU refractory patients, are as follows:***
>
> **OVERALL RESPONSE RATE**:
>
> **ALL EVALUABLE PATIENTS (n=35)**

Group	***n***	***CR n (%)***	***PR n (%)***	***Duration of Response***	***≥ SD (min 12 wks) n (%) p=0.036***
P-CAP	20	1 (5%)	3 (15%)	CR: 36m PR: 21, 19, 11 m	11 (55%)
CAP	15	0	1 (7%)	PR: 7 m	5 (33%)

> **5-FU REFRACTORY PATIENTS (n=25)**

Group	***n***	***PR n (%)***	***Duration of Response***	***≥ SD (min 12 wks) n (%) p=0.066***
P-CAP	14	1 (7%)	19 m	8 (57%)
CAP	11	0	-	3 (27%)

> **TIME TO PROGRESSION AND OVERALL SURVIVAL:**
> **ALL EVALUABLE PATIENTS (n=38)**

Group	***n***	***Median TTP Weeks p<0.001 HR: 0.254***	***Median OS* Months p=0.0052 HR: 0.370***
P-CAP	20	27.5 [95% CI (12.1-48.1)]	17.7 [95% CI (8.5-24.6)]
CAP	18	10.1 [95% CI (6.6-13.0)]	7.6 [95% CI (5.0-16.3)]

5-FU REFRACTORY PATIENTS (n=27)

Group	***n***	***Median TTP Weeks p<0.001 HR: 0.170***	***Median OS* Months P=0.0061 HR: 0.295***
P-CAP	14	17.6 [95% CI (12.0-36.0)]	15.1 [95% CI (7.2-22.3)]
CAP	13	9.0 [95% CI (6.6-11.0)]	6.5 [95% CI (4.8-10.9)]

*Survival is calculated from date of randomization until the date of death from any cause, whether or not additional therapies were received after removal from treatment.

160. The aforementioned statements in ¶ 159 were false and/or materially misleading when made because:

a. Defendants knew or recklessly disregarded the fact that the Phase 2 protocol had been manipulated so that the protocol would maximize the results observed after the initial unblinding of the data and unplanned and undisclosed interim analysis as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

b. Defendants knew or recklessly disregarded the fact that Defendants had neither disclosed nor adjusted the Phase 2 results for the multiple testing and other multiplicity issues that resulted from Defendants' data mining as explained above in ¶¶ 34-54. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA;

c. Defendants knew or recklessly disregarded the fact that Phase 2 results for the subgroup data had not been properly adjusted for multiple testing and other multiplicity

issues resulting from Defendants' data mining as explained above in ¶¶ 34-54, and failed to disclose the number of subgroup analyses performed or the results of these other sub-groups. Therefore, the Phase 2 results were not statistically significant and/or the statistical significance of the results was grossly overstated, thereby misleading investors as to (i) the probability that perifosine had been effective in treating colorectal cancer, (ii) the probability that the reported results were little more than false positives, and (iii) the likelihood that perifosine would be approved by the FDA; and

d. Defendants knew or recklessly disregarded the fact that the 13 patients enrolled in the second stage of Phase 2 after the unblinding of the initial 25 patients and interim analysis did not show any significant increase in overall survival rate, but failed to disclose this fact even though they represented that perifosine treatment combined with capecitabine produced a statistically significant increase in overall survival rates for colorectal cancer patients.

161. The 2011 10-K was also certified by Defendant Bentsur, who respectively attested to the accuracy thereof in the same form and content, except for the date of the report, set forth in ¶ 79 preceding with respect to the 2009 10-K.

162. Additionally, Defendant Bentsur certified under Section 906 of the Sarbanes-Oxley Act of 2002 that the "information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

VII. THE TRUTH EMERGES

163. On April 2, 2012, the Company shocked the market by issuing a press release that announced, in part, the following:

> NEW YORK, April 2, 2012 /PRNewswire/ -- Keryx Biopharmaceuticals, Inc. (NASDAQ: KERX) reported today that the Phase 3 "X-PECT" (***X**eloda*® + ***P**erifosine **E**valuation in **C**olorectal cancer **T**reatment)* clinical trial evaluating perifosine (KRX-0401) + capecitabine (Xeloda) in patients with refractory advanced colorectal cancer did

not meet the primary endpoint of improving overall survival versus capecitabine + placebo.

This Phase 3 trial was conducted pursuant to a Special Protocol Assessment (SPA) agreement with the FDA. 468 patients at sixty-five U.S. sites participated in this study.

164. On this news, the Company's common stock declined $3.24 per share, or approximately 65%, to close on April 2, 2012 at $1.74 per share, on unusually heavy trading volume.

165. On May 7, 2012, Keryx executed a License Termination and Technology Transfer Agreement with Æterna, whereby the Company terminated the KRX-0401 (perifosine) license agreement and gave all license rights back to Æterna. In exchange for the transfer of the U.S. Investigational New Drug Application, development data, intellectual property, and contracts to Æterna, Æterna assumed all future costs related to the perifosine program while Keryx stood to receive a low single-digit royalty on future net sales of perifosine in the United States, Canada and Mexico.

VIII. ADDITIONAL SCIENTER ALLEGATIONS

166. The development of perifosine was conducted pursuant to the License Agreement between Keryx and Æterna. Under the License Agreement, Keryx and Æterna each have the right to appoint two "professionally and technically qualified" members of the Coordination Committee which was responsible for all clinical and pre-clinical studies conducted on perifosine, including the "[t]he tasks and timing for the Pharmaceutical Development of Perifosine." By definition, under the Addendum to the License Agreement, the "Pharmaceutical Development" of perifosine included the "scale-up trials and production of drug materials for use in clinical trials, equipment and process validation, qualification of materials, stability and compatibility testing of the API and Drug Product, ***as well as development and validation of analytical methodology necessary to process validation and product release testing***." All

amendments or changes to the development plan for perifosine required the approval of the Coordination Committee. All decisions of the Coordination Committee required the unanimous consent of each of the members of the Committee. If a unanimous agreement could not be reached on any matter by the Coordination Committee, the issue was referred to a "personal face-to-face meeting" between the Æterna's CEO Jüergen Engel and Defendant Bentsur.

167. Given that Keryx's entire corporate existence revolved around drug development, testing and statistical analysis of such testing, anyone that was "professionally and technically qualified" to serve on the Coordination Committee would have known that the Phase 2 testing of perifosine was flawed and the statistical results and reports relating thereto were manipulated to misrepresent the statistical significance of the purported clinical benefit to colorectal cancer patients. Nevertheless, Defendants allowed these flawed Phase 2 results to form the foundation of the Phase 3 study; they repeatedly misrepresented to investors the statistical significance of the Phase 2 results concerning perifosine's purported benefit to colorectal cancer patients; and they failed to disclose information regarding the manipulation of the Phase 2 protocol, multiple testing arms and the results thereof, multiple ad hoc statistical analyses and subgroup analyses which were required in order to make their public statements not false and misleading.

168. Bentsur also knew, based on his business acumen and professional experience, that if he did not take extreme measures to raise funds and create public confidence in the Company's development of perifosine, one of its two leading drug candidates, the continued viability of the Company would be at stake.

169. Additionally, on September 14, 2009, Keryx and Bentsur entered into an Employment Agreement that retroactively became effective on May 20, 2009, when Bentsur became Keryx's CEO. The Employment Agreement called for a base salary of $300,000, an

annual bonus not to exceed 75% of his base salary, and an initial options grant of 600,000 shares. The Employment Agreement also includes Milestone-Based Incentive Compensation, including the following:

1. **$1.00 Share Price Milestone**. Upon first achievement of a **$1.00 share price for 120 consecutive days** (based upon average closing price of the Company's common stock on NASDAQ for a 120-day period after the Effective Date), Executive will be granted **100,000** shares of restricted stock, which will vest in equal installments over each of the first three anniversaries the date of grant provided that Executive remains an employee of the Company during such vesting period, subject to acceleration under Sections 7 and 8 of this Agreement.

2. **$2.50 Share Price Milestone**. Upon first achievement of a **$2.50 share price for 120 consecutive days** (based upon average closing price of the Company's common stock on NASDAQ for a 120-day period after the Effective Date), Executive will be granted **250,000** shares of restricted stock, which will vest in equal installments over each of the first three anniversaries the date of grant provided that Executive remains an employee of the Company during such vesting period, subject to acceleration under Sections 7 and 8 of this Agreement. Achievement of milestone #2 also will result in the achievement of milestone #1, to the extent that milestone #1 had not previously been achieved and will result in 100,000 shares of restricted stock immediately vesting upon the achievement of Milestone 2.

3. **NDA Milestone**. Upon the first to occur of (a) the Company's filing of an accepted new drug application (NDA) with the U.S. Food and Drug Administration (FDA) for Zerenex or Perifosine, or (b) the Company's outlicensing of Zerenex or Perifosine in the U.S. to a third party, provided that the license is approved by the Board and grants to the third party the right to file an NDA with respect to Zerenex or Perifosine, then Executive will be granted **400,000** shares of restricted stock, which will vest in equal installments over each of the first three anniversaries the date of grant provided that Executive remains an employee of the Company during such vesting period, subject to acceleration under Sections 7 and 8 of this Agreement. This milestone #3 may be achieved with respect to NDAs or qualifying outlicenses for multiple indications of the same product; provided that if this milestone #3 is earned with respect to an indication of a product, it shall not be earned again upon subsequent outlicense of the product relating to such indication.

4. **Commercial Sales Milestone**. Upon the first to occur of (a) the Company's first commercial sale of Zerenex or Perifosine in the U.S. off of an approved NDA, (b) the Company's receipt of the first royalty upon the commercial sale of Zerenex or Perifosine in the U.S. by a partner to whom the Company has sold exclusive or non-exclusive commercial rights, or (c) the Company's complete outlicensing of the entire product rights of Zerenex or Perifosine in the U.S., as approved by the Board, then Executive will be granted **500,000** shares of restricted stock, which will vest on the

first anniversary of the date of grant provided that Executive remains an employee of the Company during such vesting period, subject to acceleration under Sections 7 and 8 of this Agreement. This milestone #4 may be earned both for Zerenex and for Perifosine. Upon achievement of this milestone #4 with respect to a product, the restricted stock granted for one (and only one) indication of the product under milestone #3 will vest in full.

5. **Foreign Market Licensing Milestone**. Upon each event of the Company's outlicensing Zerenex in a foreign market, other than Japan, resulting in a greater than $10 million non-refundable cash payment to the Company with a gross deal value to the Company of at least $50 million, Executive will be granted **100,000** shares of restricted stock, which will vest in equal installments over each of the first three anniversaries the date of grant provided that Executive remains an employee of the Company during such vesting period, subject to acceleration under Sections 7 and 8 of this Agreement.

170. On September 22, 2009, Mr. Bentsur was granted 100,000 shares for the achievement of a $1.00 share price of the Company's common stock for 120 consecutive days. The 100,000 shares were to vest in equal installments over each of the first three anniversaries of the date of grant provided that Bentsur remained an employee of the Company ***or*** if the $2.50 milestone was achieved.

171. As of March 31, 2010, Bentsur was granted 250,000 shares for the achievement of a $2.50 share price of the Company's common stock for 120 consecutive days. The 250,000 shares were to vest in equal installments over each of the first three anniversaries of the date of grant provided that Bentsur remained an employee of the Company. Further, the initial 100,000 shares issued for the achievement of a $1.00 share price referenced in ¶ 169 automatically vested as of March 31, 2010.

172. On March 24, 2010, Bentsur sold 31,089 of his Keryx common stock at $2.95 per share for gross proceeds of approximately $91,713. On December 2, 2010 and December 3, 2010, Bentsur sold 255,560 common stock shares at approximately $5.05 and $5.01 respectfully for gross proceeds of approximately $1,288,578. On March 24, 2011, Bentsur sold 28,791 of his

Keryx common stock at $4.78 per share for gross proceeds of approximately $137,621. Finally, on January 3, 2012, Bentsur sold 3,305 of his Keryx common stock shares at $2.625 per share for gross proceeds of approximately $8,676. During the Class Period, Bentsur sold a total of 318,745 shares of Keryx common stock for total gross proceeds of approximately $1,526,588.

173. Further, Defendant Bentsur holds a Bachelor of Arts degree in Economics and Business Administration, with distinction, from the Hebrew University of Jerusalem, Israel and a Masters of Business Administration, magna cum laude, from New York University's Stern Graduate School of Business. From June 1994 to July 1998, Bentsur worked as an investment banker primarily at ING Barings Furman Selz, after which he served as Director of Technology Investment Banking at Leumi Underwriters until October 2000. In 2000, Bentsur joined Keryx and served as the Company's CFO from June 2003 to January 2006. From January 2006 to April 2009, Bentsur served as XTL Biopharmaceuticals, Inc.'s Chief Executive Officer. Bentsur then returned to Keryx in May 2009 and has served as the Company's CEO to date.

174. In early 2009, just before Keryx began to praise the positive data in its Phase 2 trial for perifosine, Keryx was still adjusting to the 2008 Restructuring following the failure of Sulonex™—one of the Company's primary drug candidates in Phase 3 testing—and a stock price that was languishing to the point that the Company was facing de-listing by the NASDAQ CM. Furthermore, the Company has not commercialized any of its drug candidates and has incurred substantial operating losses since its inception. By June of 2009, the Company had $13.4 million in cash and cash equivalents, along with $7.1 million of auction rate securities. On June 9, 2009, analyst John Eade with Argus Research Company made the following remarks: "[t]he Company still doesn't have enough cash or product revenue to assure operations through 2010" and "[w]e think the company has enough cash to fund operations for only about six

months, based on its current burn rate, and we expect it to have great difficulty raising additional capital . . .”

175. As a result of Defendants’ misleading and/or false statements regarding the true efficacy of perifosine in treating colorectal cancer, throughout the duration of the Class Period, the Company was able to sell, at artificially inflated prices, approximately 15 million shares of Company common stocks and warrants through registered direct offerings and underwritten registered direct offerings generating gross proceeds of approximately $53 million. The Company’s continued financial viability was dependent upon the completion of these secondary offerings.

IX. LOSS CAUSATION

176. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated Keryx’s stock price and operated as a fraud or deceit on Class Period purchasers of Keryx securities by misrepresenting the Company’s business and prospects. During the Class Period, Defendants misrepresented and concealed the true facts regarding the likelihood of the clinical success of perifosine to treat colorectal cancer. Later, however, as Defendants’ prior misrepresentations and omissions were disclosed and became apparent to the market, the price of Keryx stock fell precipitously. As a result of purchasing or selling Keryx securities during the Class Period at artificially inflated prices, Plaintiff and other Class Members suffered damages as the truth regarding Keryx’s failure to achieve clinical success for perifosine to treat colorectal cancer was revealed.

177. Defendants’ wrongful conduct, as alleged herein, directly and proximately caused the damages suffered by Plaintiff and the Class.

178. Defendants’ false and misleading statements and omissions in their SEC filings and other public statements during the Class Period directly caused losses to Plaintiff and the

Class. On the strength of these false statements, the Company's stock price was artificially inflated to a Class Period high of $6.67 per share on May 4, 2010. Those misrepresentations and omissions that were not immediately followed by an upward movement in the Company's stock price served to maintain the share price at artificially inflated levels by maintaining and supporting a false positive perception of Keryx's business, operations, performance and prospects. All daily trading prices and volumes for publicly traded Keryx stock are incorporated by reference herein.

179. As the truth began to emerge regarding the true nature of the efficacy of perifosine in treating colorectal cancer, the price of Keryx stock declined as the market processed each set of previously undisclosed facts. Each such disclosure removed a portion of the artificial inflation in the price of Keryx's securities and directly caused Plaintiff and other Class members to suffer damages. On April 2, 2012, Keryx's stock had declined to a close of $1.74 per share – a decline of approximately 73% per share from its Class Period high.

180. Until shortly before Plaintiff filed this Complaint, he was unaware of the facts alleged herein and could not have reasonably discovered the Defendants' misrepresentations and omissions by the exercise of reasonable diligence.

X. CONTROL PERSON LIABILITY

181. Bentsur is liable as a direct participant with respect to the wrongs complained of herein. In addition, Bentsur, by reason of his status as a senior executive officer and/or director, was a "controlling person" within the meaning of Section 20(a) of the Exchange Act, and had the power and influence to cause the Company to engage in the unlawful conduct complained of herein. Because of his positions of control, Bentsur was able to and did, directly or indirectly, control the conduct of Keryx's business.

182. Specifically, because of his position within the Company, Bentsur possessed the power and authority to control the contents of Keryx's annual and quarterly reports, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market, including those containing the materially false and misleading statements and omissions of material fact alleged herein. Bentsur, by reason of his respective management or board position, had the ability and opportunity to review copies of the Company's SEC filings, reports and press releases alleged herein to be misleading, prior to, or shortly after their issuance or to cause them to be corrected.

183. By virtue of his position, Bentsur had access to material non-public information. Bentsur knew or recklessly disregarded the fact that the adverse facts specified herein had not been disclosed and were being concealed from the public, and that the positive representations which were being made were then materially false and misleading.

XI. APPLICABILITY OF THE FRAUD ON THE MARKET DOCTRINE

184. At all relevant times, the market for Keryx's securities was an efficient market for the following reasons, among others:

a. Keryx's stock was listed and actively traded on the NASDAQ CM, a highly efficient national markets;

b. As a registered and regulated issuer of securities, Keryx filed periodic reports with the SEC, in addition to the frequent voluntary dissemination of information;

c. Keryx regularly communicated with public investors through established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures such as communications with the financial press and other similar reporting services;

d. Keryx was followed by multiple analysts, which followed Keryx's business and wrote reports which were publicly available and affected the public marketplace;

e. The material misrepresentations and omissions alleged herein would tend to induce a reasonable investor to misjudge the value of Keryx's stock; and

f. Without knowledge of the misrepresented or omitted facts, Plaintiff and other members of the Class purchased or otherwise acquired Keryx stock between the time the Defendants made the material misrepresentations and omissions and the time that the truth was revealed, during which time the price of Keryx stock was artificially inflated by Defendants' misrepresentations and omissions.

185. As a result of the above, the market for Keryx securities promptly digested current information with respect to the Company from all publicly available sources and reflected such information in the security's price. Under these circumstances, all purchasers of Keryx securities during the Class Period suffered similar injuries through their purchases and/or sales of Keryx securities at prices which were artificially inflated by the Defendants' misrepresentations and omissions. Thus, a presumption of reliance applies.

XII. THE *AFFILIATED UTE* PRESUMPTION

186. At all relevant times, Plaintiff and the Class reasonably relied upon Defendants to disclose material information as required by law and in the Company's SEC filings. Plaintiff and the Class would not have purchased or otherwise acquired Keryx securities at artificially inflated prices if Defendants had disclosed all material information as required. Thus, to the extent Defendants wrongfully failed to disclose material information concerning perifosine's clinical trials with the likelihood of the clinical success of perifosine in treating colorectal cancer, Plaintiff and the Class are presumed to rely on Defendants' omissions as established by the Supreme Court in *Affiliated Ute Citizens v. U.S.*, 406 U.S. 128 (1972).

XIII. NO SAFE HARBOR

187. As alleged herein, Defendants acted with scienter because, at the time that they issued public documents and other statements in Keryx's name, they knew or recklessly disregarded the fact that such statements were materially false and misleading or omitted material fact. Moreover, Defendants knew that such documents and statements would be issued

or disseminated to the investing public; knew that persons were likely to rely upon those misrepresentations and omissions; and knowingly and/or recklessly participated in the issuance and/or dissemination of such statements and/or documents as primary violators of the federal securities laws.

188. As set forth in detail in this Complaint, Bentsur, by virtue of his control over, and/or receipt of Keryx's materially misleading statements and/or his association with the Company which made him privy to confidential proprietary information concerning Keryx which was used to artificially inflate financial prospects and which Bentsur caused or was informed of, participated in and knew of the fraudulent scheme alleged herein. With respect to non-forward looking statements and/or omissions, Bentsur knew and/or recklessly disregarded the false and misleading nature of that information, which he caused to be disseminated to the investing public.

189. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made and/or were statements of historical fact. Rather, all the statements alleged herein to be false and misleading relate to facts and conditions existing at the time the statements were made. Moreover, meaningful statements did not identify important factors that could cause actual results to differ materially from those in any putative forward-looking statement.

190. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular

speaker knew that the particular forward-looking statement was false, and/or the forward-looking statement was authorized and/or approved by an executive officer of Keryx who knew that those statements were false when made. None of the historic or present tense statements made by Defendants were an assumption underlying or relating to any plan, projection, or statement of future economic performance, as they were neither stated to be such an assumption underlying or relating to any projection or statement of future economic performance when made nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

XIV. CAUSES OF ACTION

COUNT I

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

191. Plaintiff realleges each allegation above as if fully set forth herein.

192. This claim is brought under Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5, against Keryx and Bentsur. Defendants (1) employed devices, schemes and artifices to defraud; (2) made untrue statements of material fact and/or omitted material facts necessary to make the statements made not misleading; and (3) engaged in acts, practices and a course of business which operated as a fraud and deceit upon Plaintiff and the Class, in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

193. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or the mails, engaged and participated in a continuous course of conduct to conceal non-public, adverse material information about the

Company's financial condition or prospects as reflected in the misrepresentations and omissions set forth above.

194. Defendants each had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth by failing to ascertain and to disclose such facts even though such facts were available to them, or deliberately refrained from taking steps necessary to discover whether the material facts were false or misleading.

195. As a result of Defendants' dissemination of materially false and misleading information and their failure to disclose material facts, Plaintiff and the Class were misled into believing that the Company's financial statements and other disclosures were true, accurate, and complete.

196. Plaintiff and the Class either purchased Keryx securities, without knowing that the Defendants had misstated or omitted material facts about the Company's financial performance or prospects. In so doing, Plaintiff and the Class relied directly or indirectly on false and misleading statements made by Defendants, and/or an absence of material adverse information that was known to Defendants or recklessly disregarded by them but not disclosed in Defendants' public statements. Plaintiff and the Class were damaged as a result of their reliance on Defendants' false statements and misrepresentations and omissions of material facts.

197. At the time of Defendants' false statements, misrepresentations and omissions, Plaintiff and the Class were ignorant of their falsity and believed them to be true. Plaintiff and the Class would not otherwise have purchased or acquired Keryx securities had they known the truth about the matters discussed above.

198. Plaintiff is filing this action within two years after discovery of the facts constituting the violation, including facts establishing scienter and other elements of Plaintiff's claim, and within five years after the violations with respect to Plaintiff's investments.

199. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

200. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the Class have suffered damages in connection with the purchase of Keryx securities.

COUNT II

For Violations of Section 20(a) of the Exchange Act Against Bentsur

201. Plaintiff realleges each allegation above as if fully set forth herein.

202. Bentsur, by reason of his status as a senior executive, officer, controlling shareholder and/or director of Keryx, directly or indirectly, controlled the conduct of the Company's business and its representations to Plaintiff and the Class, within the meaning of Section 20(a) of the Exchange Act. Bentsur directly or indirectly controlled the content of the Company's SEC statements and press releases related to Plaintiff's and the Class' investments in Keryx securities within the meaning of Section 20(a) of the Exchange Act. Therefore, Bentsur is jointly and severally liable for the Company's fraud, as alleged herein.

203. Bentsur controlled and had the authority to control the content of the Company's SEC statements and press releases. Because of his close involvement in the everyday activities of the Company, and because of his wide-ranging supervisory authority, Bentsur reviewed or had the opportunity to review these documents prior to their issuance, or could have prevented their issuance or caused them to be corrected.

204. Bentsur knew or recklessly disregarded the fact that Keryx's representations were materially false and misleading and/or omitted material facts when made. In so doing, Bentsur did not act in good faith.

205. By virtue of his high-level positions and his participation in and awareness of Keryx's operations and public statements, Bentsur was able to and did influence and control Keryx's decision-making, including controlling the content and dissemination of the documents that Plaintiff and the Class contends contained materially false and misleading information and on which Plaintiff and the Class relied.

206. Bentsur had the power to control or influence the statements made giving rise to the securities violations alleged herein, and as set forth more fully above.

207. As set forth above, the Defendants each violated Section 10(b) of the Exchange Act and Rule 10b-5, thereunder, by their acts and omissions as alleged herein. By virtue of his position as a controlling person, Bentsur is also liable pursuant to Section 20(a) of the Exchange Act.

208. As a direct and proximate result of Bentsur's wrongful conduct, Plaintiff and the Class suffered damages in connection with their purchase of Keryx securities.

XV. PRAYER FOR RELIEF

WHEREFORE, Plaintiff on behalf of himself and the Class, prays for relief and judgment including:

A. Determining that Counts I and II of this action constitute a proper class action under Federal Rules of Civil Procedure 23, certifying Plaintiff as a Class representative under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff's counsel as Lead Counsel;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be determined at trial, including pre-judgment and post-judgment interest, as allowed by law;

C. Awarding extraordinary, equitable and/or injunctive relief as permitted by law (including, but not limited to, rescission);

D. Awarding Plaintiff and the Class their costs and expenses incurred in this action, including reasonable counsel fees and expert fees; and

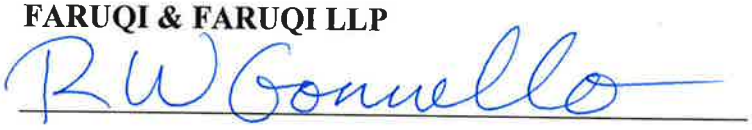
E. Awarding such other and further relief as may be just and proper.

XVI. JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury on all triable claims.

Dated: New York, NY
March 11, 2013

FARUQI & FARUQI LLP



Richard W. Gonnello
Francis P. McConville
Steven Bentsianov
369 Lexington Avenue, 10th Floor
New York, NY 10017
Tel: (212) 983-9330
Fax: (212) 983-9331
E-mail: rgonnello@faruqilaw.com
fmcconville@faruqilaw.com
sbentsianov@faruqilaw.com

Counsel for Plaintiff Arthur Smith

CERTIFICATE OF SERVICE

I hereby certify that on March 11, 2013, I caused a true and correct copy of the foregoing AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS to be served upon all defense counsel listed below via First Class Mail, postage pre-paid and via Electronic Mail:

Joseph Gerard Tully
Alston & Bird LLP
90 Park Avenue, 12th Floor
New York, NY 10016

John Allen Jordak
Alston & Bird LLP
One Atlantic Center
1201 West Peachtree Street, Suite 4200
Atlanta, GA 30309

By: _____
Steven Bentsianov